SECURING THE STRATEGIC ADVANTAGE IN BIOTECHNOLOGY

SEMINAR 3

BIOTECHNOLOGY INDUSTRY STUDY REPORT
MAY 2022

AY 2021-2022

E.S. – 6703: BIOTECHNOLOGY INDUSTRY STUDY

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Spring Seminar # 3

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Section 1 – INTRODUCTION

"The interesting thing to program in the 21st century isn't going to be computers – it's biology." – Tom Knight[1]

The United States (U.S.) is the world leader in biotechnology (biotech) and innovation. Biotech availability has increased competition in the global market, threatening America's dominance in the industry. Biotechnology is simply defined as the "application of biology for useful purposes."[2] It is not a defined list of products or industries but a set of "enabling technologies" that are industrialized and used to replace chemical compounds.[3] The biotech industry is one of the world's fastest-growing, lucrative, and expansive global markets, introducing new scientific methods and bio-products at an unprecedented pace. Research-intensive biotech corporations have effectively redefined modern medicine, enhancing health care and developing techniques to increase human performance at the molecular level.[4] Industry revenues exceed the global semiconductor market and contribute more than seven percent of America's gross domestic product (GDP).[5] Advancements in bioengineering and manufacturing led to increased agricultural, pharmaceutical, and petrochemical productivity within the U.S. This report provides an overview of the biotech industry, its application to the defense industrial base, global competition, and its impact on U.S. policy and strategy to protect national security while maintaining the leading edge in the field.

Biotechnology revolutionizes the field of genetic editing, as evidenced by the Human Genome Project (HGP), by merging engineering with life sciences to enhance the human condition. While research is limited, recent studies open new gateways to advanced genetic manipulation.[6] Ultimately, successful biotechnologies will change a living organism's ability to perform new functions and produce new materials. This level of molecular control poses several

ethical concerns and has a strong potential for malicious use. Advanced biotech has become one of the gravest threats to homeland security if it gets in the wrong hands.[7]

Ethical concerns regarding human enhancement include questions about safety, efficacy, distributive justice, and autonomy. One key question in the debate over the ethics of applying biotech for human genome modification is whether such interventions are morally acceptable. Some argue that improvements are unethical because they involve health risks and could create social inequalities. In contrast, others maintain that scientists can justify enhancements to improve quality of life and increase autonomy. A second issue is accessibility to these scientific services. Additionally, there are fears that irrational actors could use improvements for nefarious purposes, such as creating "super soldiers," enhanced biological weapons, or enhancing intelligence to gain superiority in current and future geopolitical environments.

The U.S. approach to biotech is conservative, which is evident in its restrictions on funding and practical application. U.S. law does not prohibit most genomic research, yet policies restrict the application of human gene editing technologies and prevent government funding to advance the research. The U.S. Food and Drug Administration (FDA), responsible for U.S. research funding, has strict policies against human gene editing that explicitly restrict gene modifying technologies on human embryos. Also, the National Institute of Health (NIH) has similar policies to restrict funding against technologies that result in modified inheritable genetic traits.[8] Therefore, many of these research initiatives depend on private funding. The lack of government funding for innovative biotech startups limits gene-editing research and the U.S.'s ability to compete in the global market.

While Western nations continue debating the ethics of bioengineering, China and Russia are advancing their biotech industries. China considers its biotech industry a critical component

of its long-term national security objectives. Recent Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) work conducted by He Jiankui and human germline modification experiments conducted by Dr. John Zhang indicates China's aggressive, innovative posture within their biotech industry. Additionally, it highlights the need for transnational treaties to govern ethical practices and the safe use of technology.[9] Russia has kept a close hold on the productivity of its biotech industry, although historically, they are known for their aggressive dual-use biotech research program. The Russian Biopreparat bioweapons program remained concealed within the legitimate confounds of Russia's civilian biodefense program until the late 1980s. While international law eradicated offensive biological programs globally, the U.S. intelligence community reports that both countries maintain limited offensive biological weapons capability, possibly shielded by dual-use laboratories.[*] As the U.S. and its competitors race to be the first to dominate the field of biotechnology, the U.S. must implement policies that strike a balance between legislature and ethics to manage innovation while ensuring social protection and America's competitive edge.

Section 2 – THE BIOTECH INDUSTRY

"Biotechnologies, including synthetic biology, are going to be foundational to the 21st-century economy." -- Dr. Tara O'Toole[10]

The biotech industry is rapidly growing within the U.S. economy, with revenue equaling $137.6 billion in 2021.[11] The completion of the human genome project, the development of CRISPR gene editing, and the global COVID pandemic have made the biotechnology revolution

[*] See Appendix B for a full analysis of China's Biotechnology Industry and Innovation. Refer to Appendix A and C for more information about Ukraine and Russia respectively.

a household conversation.[12,13,14] Biotechnology is "emerging as one of the leading technologies for the transition towards a carbon-free society and for solving significant societal challenges comprising health protection, food shortages, energy supply, and environmental protection."[15] Medical and industrial biotechnology applications are critical for National Security and the Department of Defense (DOD). Therefore, the biotech community continues developing and producing innovations to enhance the global economy and improve the human condition.

Section 2a – THE US BIOTECH INNOVATION BASE

The U.S. biotech innovation base is indispensable for the U.S. to maintain its global leadership in the industry. The foundation of the biotechnology innovation base is the triple helix model of innovation, which is people-driven and guided by U.S. policy and investment. It is dependent on constant interactions between academia, industry, and government agencies. As a result, the development of biotechnology clusters, a high concentration of partners within a geographical location, have been essential in achieving the highest level of innovation in the field.

To maximize the U.S. potential in biotechnology and capitalize on advancements requires a seismic shift in the way policymakers approach funding and regulating biosciences and bio-manufacturing.[16] Additionally, academia and industry must demonstrate biotechnology's current and future value for U.S. prosperity. Therefore, the biotechnology triple helix needs a strategic, aggressive, focused, and coordinated effort to reduce silos and identify synergies among federal agencies, industry, universities, and national laboratories. For a complete analysis of the biotechnology industry, refer to Appendix D.

Section 2b - HUMAN CAPITAL IN BIOTECH

There is a "global war for young talent" and China is determined to overtake America as the biotech leader by 2025.[17,18] To maintain its strategic advantage, the U.S. must implement initiatives to improve human capital within its biotech industry. Current U.S. employment in biotechnology has approximately 286,000 employees, with annual employment only growing one percent from 2016 to 2022. [19,20] With a projected employment growth rate of 2 percent over the next 4 years, the U.S. biotech sector must hire approximately 5,700 additional employees by 2026 to spread across its 7,510 biotech companies.[21,22]

Market demand in biotech is increasing and could outpace the available human capital because there is more work than there are people to do the work. Additionally, while good for innovation, the biotech industry's key clusters impede the talent pipeline. The tendency is for human capital talent to move to key biotech clusters leading to “brain drains “in other regions. For instance, Boston is experiencing a "net brain gain," meaning more highly educated people move there than leave.[23] While North Carolina, in 2017 (and many other years), experienced a "brain drain" (-6%) where more highly educated people left the state.[24] This creates a human capital talent gap between those in and out of the key clusters. Those in the cluster are moving faster than the rest of the industry, outproducing and hitting milestones earlier (i.e., being acquired or merging two years earlier than those outside a key cluster).[25] Pathways outside of the key clusters need to be developed.

Finally, U.S. restrictive immigration policies reduce the talent pool available. In 2019, international students attending U.S. colleges garnered "nearly half of all master's and doctor's Science, Technology, Engineering, and Mathematics (STEM) degrees [awarded], a total of 117,000 degrees."[26] These student visas generally expire within 60 days of graduation unless

they apply for one of the following: curricular practical training (CPT), optional practical training (OPT), STEM OPT extension, continued education on a student visa, temporary employment (like the H1-B visa), or lawful permanent residence (LPR – "also known as green card").[27] The H1-B visa has an annual cap: 65,000 "regular cap" and 20,000 "advanced degree exemption."[28] In FY2021, only 1.7 percent of the H1-B visas awarded were in life sciences, most closely aligned to the biotechnology industry.[29] The green card has a limit of "140,000 employment-based immigrant visas" available each fiscal year.[30] Therefore, the U.S. must address the current immigration policy to foster the talent available in the biotech talent pool.

Section 3 - BIOTECHNOLOGY AND THE DEFENSE INDUSTRIAL BASE

"We are obviously going to end up using biology to make everything. It is dramatically superior technology." – Dr. Jason Kelly[31]

The U.S. biotech industry is vital to national security. Strategic competition and adversarial relationships with China necessitate immediate actions to enhance biotech supply chain resilience. Maintaining safety stocks through accurate analytics and supply chain intelligence and partnerships through the National Technology Industrial Base (NTIB) will enhance resiliency while enabling the nation to compete on its terms with China.

Efficiency and profitability can no longer be the sole considerations when confronted with transnational challenges paralyzing the flow of material critical to national security. Developing a robust safety stock based on analytics and supply chain intelligence will improve overall visibility and transparency across the supply chain, reduce disruption costs, and better prepare the nation for surge, mobilization, and national crisis.

Leveraging and investing in supply chain professionals must be a top priority to enhance resiliency and flourish in the post-pandemic era. Intertwined economies, interdependency, national imperatives, and increasing transnational challenges bring novelty and complexity to resolving global supply chain issues. Further, they illuminate how vital social and analytical human capital is in analyzing and resolving supply chain challenges while building relationships with suppliers and customers for longer-term success.

In a strategic competition with China, the time for the U.S. to assume additional leadership and formalize the NTIB to reach its full potential is now. Formalizing it by adding structure, governance, resources, and oversight is the linchpin to unleashing the full potential of a group of nations recognized for mutual interests, innovation, and an abundance of talent and highly qualified human capital. Additionally, enhancing the NTIB will develop additional areas for collaboration, guide procurement processes, and counters China's efforts to control the manufacturing of critical materials.

Section 3a –DOD ACQUISITION AND PROCUREMENT OF BIOTECH

The DOD developed the Defense Acquisition System (DAS) to produce a more lethal force based on U.S. technological innovation and a culture of performance that yields a decisive and sustained military advantage.[32] Subsequently, the Adaptive Acquisition Framework was created to tailor procurement strategies and is intended to provide a set of acquisition pathways that the program manager can select to enable better warfighting solutions faster.[33]

Biotechnology is not formally recognized as a traditional sector of the defense industry. Though biotechnology offers great capabilities to enhance force lethality, the DOD regulatory landscape and oversight structure for the acquisition of biotechnology makes entering the defense marketplace difficult and prevents many innovators from working with the DOD.

Additionally, the DOD's approach to intellectual property rights is not attractive to commercial contracts. Independent biotech entrepreneurs will not compete after weighing the high risks and opportunity costs against small value creation.[34]

Despite challenges integrating biotech in other facets of the defense industry, the DOD currently recognizes biotechnology as a critical asset for human health and force health protection. The Army Medical Department (AMEDD) created the decision gate process to integrate DOD acquisition policies and FDA/EPA regulations to acquire medical products and devices.[35] The process aligns the DOD acquisition life cycle with the FDA process, budgeting, and biomedical technology readiness levels (TRLs) to ensure effective and efficient development and delivery of biomedical capabilities.

To extend biotech beyond human health, the DoD must change the acquisition culture to be more risk-tolerant by removing excessive regulatory requirements that impede progress. As Eric Du, co-founder and executive director of the Formosan Enterprise Institute suggests, the Pentagon must leverage capitalist market forces and allow biotech companies to follow their proven best practices while developing an innovative and business-minded relationship with the biotech industry.[36] Industry must also develop a narrative on the practical use of the technology to enhance force capability and lethality in future conflicts. Remaining the tier one military force requires the DOD to reevaluate and adjust its acquisition policies and regulations to set conditions for greater biotech innovation.

Section 4 - TRADE POLICY IN BIOTECH

U.S. biotech trade policy is poorly defined and complex. There are numerous definitions of biotech which creates challenges in managing trade. With global biotech expected to grow to $2.44 trillion by 2028, it is imperative to develop a shared understanding.[37]

The U.S. biotech industry has significant trade issues such as production costs, protection of intellectual property, and inflation. The pandemic and resulting supply chain crisis exposed the national security risk of requiring the production of essential products outside the U.S. This offshore production also increases the risk of intellectual property theft as competing nations can reverse-engineer these products manufactured in their factories. The strength of the U.S. dollar in the global economy increases the cost of manufacturing products in the U.S. and the price of exporting American bioproducts.

While many believe biotech only consists of pharmaceuticals, it also includes agriculture, biochemicals, biotextiles, bioleaching, biofuels, medical devices, and support products.[38] These sectors combined make up the bioeconomy. A literature review of 15 research articles published between 2000 and 2019 found that 26 general and specific industries were included, fully or partially, as part of the bioeconomy and ranged from crop production to research & development to mining (bioleaching) to tourism.[39,40]

Biotech represents one of the most competitive international trade markets, and the world understands this industry supports the basic human needs for medicine, food, and energy.[41] Additionally, the industry will be helpful in the ongoing climate crisis battle, particularly with biofuels, biochemicals, and biofuel crops.[42] The global climate change crisis is expected to continue to drive this sector in the future.[43]

Internationally, the medical treatment sector of biotechnology accounts for 51.3 percent of trade.[44] The second largest sector is called resource industries, including fuels and chemicals supporting fuel systems, at 19.8 percent.[45] Agriculture products were formerly a larger sector for international trade, with America as the primary exporter. However, concerns with genetically modified food, especially in Europe, have decreased this trade to 14.7 percent of the global bioeconomy.[46] The remaining 14.2 percent of the worldwide market includes industrial biochemicals, biotextiles, bioproducts to regulate ecosystems, and bioinformatics (obtaining, storing, analyzing, and separating biological information).[47]

The U.S. government needs biotech to continue to grow as a major industry for the economy. Therefore, the government has a role in creating new trade laws and continued enforcement of existing trade laws, including export controls, tariff management, industrial espionage, and intellectual property protection. Severe punitive consequences must be enforced to protect American companies, especially in dealings with China.[48]

Section 4a - INTELLECTUAL PROPERTY, PATENTS, AND TECH TRANSFER

The U.S. must evaluate future policy and legal strategies to ensure continued partnerships and growth without the risk of losing the competitive edge amongst partner and competitor nations. The U.S. can effectively protect biotech intellectual property, manage patents, and organize technology transfer by maximizing information, regularly reviewing patent laws, and streamlining biotech development pipelines.

Accordingly, the U.S. needs to add more protections for the biotech industry. This can be accomplished by implementing the March 2021 recommendations of the Commission on the Theft of American Intellectual Property.[49] Additionally, the U.S. can increase oversight of academic programs for all international students to support training and retaining these young

professionals and counter industrial espionage in American research and development (R&D) facilities. Continuing federal investment and assistance are needed through public-private partnerships to support continued innovation. America maintaining its lead in biotech weakens the economic power of many of America's adversaries, especially those nations that profit from the fossil fuel trade.[50]

The U.S. changed patent laws in 2011 via the Leahy-Smith America Invents Act. This effort synchronized the law to coincide with most other nations' "first to file" versus the U.S.'s previous "first to invent" model. The average timeline for gaining a U.S. patent is 22 months, and it remains in effect for 20 years for biotechnology. This timeline coincides with many member nations of the World Trade Organization (WTO). The U.S. Patent and Trademark Office maintains multiple programs to facilitate domestic and international intellectual property management, and the WTO manages a dispute system for the same. Finally, the Department of the Treasury chairs the Committee on Foreign Investments in the United States (CFIUS), which oversees, amongst other things, technology transfer.

The U.S. must lead the WTO in developing more definitive international systems for patent and trademark management and filing. This system would ensure partner nations have an equal opportunity while helping to protect U.S. interests. Additionally, the U.S. should use technology transfer as a diplomatic tool to promote good behavior and punish bad behavior. Technology transfer can incentivize foreign governments' actions. The threat of removing transferred technology can be used as a deterrent and a punitive measure like economic sanctions.

Section 5 - DISRUPTIVE BIOTECHNOLOGY AND BIOSECURITY

The biotech field has and will continue to benefit from an exponential increase in data storage and computer processing power. Biological science progress drives innovation that drastically affects economies and societies ranging from health and agriculture to consumer goods and energy.[51] Foundational science from projects such as the HGP has significantly reduced the cost of mapping the human genome over the last 20 years.[52] Thus, data will fuel a biological revolution that will reduce the disease burden and improve public health, human performance, quality of life, the environment, and manufacturing efficiency.

The highly competitive biotech industry will exploit emerging technologies, such as AI, machine learning, robotics, additive manufacturing, microsensors, and big data analytics, to improve research and development (R&D) and bring new products to market more quickly, safely, and cheaper. R&D on the frontiers of biotech is creating emerging disruptive technologies. Genetic screening for disease, recombinant protein production, Chimeric Antigen Receptor (CAR) T-Cell therapy, and gene therapy are some examples of current disruptive biotechnologies that have improved lives. Genome editing with the CRISPR and the CRISPR-associated protein 9 (Cas9) system has proven highly effective in developing new, more effective, or more efficient products. Maturation of messenger RiboNucleic Acid (mRNA) technology-enabled vaccine development to prevent the spread of the COVID-19 pandemic.

Synthetic Biology (SynBio) is another emerging disruptive technology like gene editing that uses biological engineering to improve agriculture, medicine, and manufacturing. Biotech research continues to advance in the microbiology subfields of proteomics, transcriptomics, metabolomics, lipidomics, and microbiomics to improve the understanding of cell biology at a

resolution that has never been possible. Research in the "-omics" disciplines will complement genomics with the potential to be disruptive as they mature.

Biotech offers great opportunities, but it also comes with threats. Intellectual property theft, inconsistent regulatory frameworks, and controversial ethical guidelines and standards threaten the health of the biotech industry and the safety and efficacy of products it creates.[†]

Section 5a – BIOSECURITY: SECURING THE BIO-ECONOMY

Bringing science into the digital age allows the four major small molecule nucleotides: adenine, cytosine, thymine, and guanine, to be coded as a zero or a one and enables them to be stored and processed like information flowing across a computer screen.[53] An example of this advancement is the HGP, which showcased its results in 2003 at the cost of $10.5 billion. Almost twenty years later, the price for an individual to map their DNA genetic sequence today is less than $1000 and can be completed in mere hours. As life-altering as this type of innovation can be, there are resulting threats to U.S. national security, just like all dual-use technologies.

No discussion of biosecurity is complete without expanding on CRISPR technology. This 2013 discovery earned the Nobel Prize in chemistry and identified a repetitive DNA sequence of bacterial genomes which allows for defense against viruses.[54] Its finding allows for genetic engineering and recrafting the makeup of human life to be streamlined in an exponentially simpler way than before. As an oversimplification, its benefit has been analogized to the ease of using a word processor to edit a document by cutting and pasting large text rather than writing by hand to conduct genetic experiments.

[†]See Appendix E for a second example of disruptive technology in the field of human enhancement.

CRISPR applications and its associated protein "CAS-9" are numerous. The commercialization and democratization of technology are symbolic of the double-edged sword nature of innovation and must remain a concern for national security. By using this process to edit DNA and RNA, i.e., the "software of life," there appear to be few limits to what this technology can produce, for better or worse.

Section 5b - ETHICAL CONSIDERATIONS IN BIOTECH

As healthcare and biotech rapidly advance, ethical issues have increased just as quickly. One of the most pressing bioethical topics up for debate today is how to properly handle personal and sensitive genetic and medical data. New developments in science and technology (S&T) have focused attention on topics such as assisted reproductive technologies, neurotechnology or brain manipulation ethics, nanotechnologies, precision medicine, agricultural and environmental advances, the longevity of human life, genetic testing, and privacy of data, stem cells, and a host of other subjects.

Using different ethical frameworks influenced by the environment, society, and culture produces moral norms deemed as commonsense that are, ironically, not so common to everyone. This results in disagreements, debates, and conflict. Ethical standards are born out of the societal change and appetite at the time and reflect the personal beliefs of national leaders to guide policy and legislative decisions. These decisions are also regionally specific in a world where countries are not necessarily operating by the same ethical and moral rules. Each of them is gambling with national security, great power competition, global economic and geopolitical control, and the protection of their citizens.

In 2018 a National Biodefense Strategy was published to align with the National Security Strategy, recognizing the growing risks of biological incidents, accidental or intentional. The

second goal of the strategy is to ensure biodefense enterprise capabilities to prevent bio incidents. The strategy says, "This goal also recognizes the "dual-use" natures of the life sciences and biotechnology, in which the same S&T base that improves health, promotes innovation, and protects the environment, can also be misused to facilitate a biological attack. The United States seeks to prevent the misuse of S&T while promoting and enhancing legitimate use and innovation."[55]

Legacy rules are not sufficient, nor do they keep up with the pace of our adversaries. The gap in U.S. vulnerabilities is growing, and the U.S. must take bold action and establish a grand strategy to get ahead of rapidly moving biotechnology, laws, ethics, and global interconnectivity before they crash and result in irreparable destruction. Further, the U.S. must assert leadership, influence, and precedence worldwide to educate the masses, establish oversight, mitigate risk, and, if need be, disarm those who are not acting in good faith for the greater good.

The benefits of biochemical, pharmaceutical, and other technological advances can be tremendously rewarding and alter how humans live and co-exist. However, the consequences of nefarious acts could be catastrophic. The U.S. can counter the effects with a greater understanding of adversarial capabilities and the art of the possible, protection of patient data and consent, and global collaboration, agreements, and consensus on proper and intended use, for the greater common good.

There is a growing concern that well-intentioned precision medicine and targeted health treatments could be exploited into precision bioterrorism with high consequence pathogens. Potential bad actors could use genetic biomarkers to target a population and customize their attack according to their genetic makeup, DNA, or medical data, of which no one has control or

the ability to change. This leaves millions of citizens unaware and defenseless against such an attack.

The connection between bioethics and law in the U.S. and other countries raises several challenges. It is important to consider that the law usually does not change as quickly as science or societal values in trying to foretell the future of bioethics and law. Because law frequently lags in these areas, individuals working in law need to consider that today's law is not addressing the scientific or bioethics problems of yesterday. Laws need to be reassessed continually and, if necessary, revised to reflect current conditions. A bioethics commission appointed by this administration could advance analyses of existing technologies whose rapid development continues to raise unresolved issues. Genetic and genomic technologies, for example, offer an expanding range of predictive and screening tools, including direct-to-consumer tests, with continuing debate over appropriate uses and safeguards.

Meanwhile, emerging technologies that can alter the genetic makeup of animals and human beings challenge current oversight systems to protect responsible innovation while preventing abuse. For example, in health and science policy, there is tension between the importance of individual autonomy and the potential for significant societal benefit. Policy makers must consider social protections while setting the necessary conditions to advance the science for societal benefit (i.e., finding cures for diseases or injury-prevention strategies).

The U.S. needs to take bold action to strengthen biosafety and biosecurity practices and oversight to detect, contain, and prevent risks of biological incidents. It also needs to support the responsible conduct of biomedical innovation. Despite vastly different moral, ethical, theological, and geopolitical beliefs, there needs to be consensus on practical and responsible use. Our adversaries' use of advanced biological weapons is a current and realistic national

security concern for the U.S., as state and non-state actors look to increase their political and economic influence and power across the globe. Global security will be achieved only by building stable and robust societies.

Section 5c - THE BIOTECH REGULATORY LANDSCAPE

While the U.S. has been the world leader in biotechnological expertise and innovation, China is investing heavily in the industry to take over the dominant position.[56] Since the 1990s, the Five-Year Plans for the National Economic and Social Development of the People's Republic of China have emphasized an aggressive strategy to become the world leader in biotechnology. This raises the question, does the U.S. have the proper regulatory framework and guidelines to maintain its dominance and competitive edge in biotechnology?

In 1976 the NIH published an initial set of research guidelines based on scientists' concerns regarding recombinant DNA technology research oversight.[57] While Congress considered various proposals for unified biotechnology legislation, they did not enact any federal regulation until 1984 with the first coordinated framework for the regulation of biotechnology. The new framework defined the biotechnology-related responsibilities of the multiple federal agencies involved. In 1992, the framework was updated to provide agencies with a risk-based, scientifically sound method for regulating biotech products. The update directed that products intended for use should not be regulated based on the process by which they were made; instead, the criteria would be "characteristics of the organism, the target environment, and the type of application."[58] This decision separates the U.S. from most other countries globally and enables the U.S. to remain the world's leader in the biotech industry. Regulating the product versus the means used to make a product encourages innovation and experimentation.

The future of biotech potentially holds the solutions to national security concerns such as climate change, food scarcity, environmental sustainability, and human performance. To be effective in technological developments and scientific uncertainty, the U.S. regulatory system for biotech must be flexible, responsive to scientific discovery, transparent, and risk management focused.[59] Despite the enormous potential benefits, the U.S. biotech industry has not reached its full potential due to the tedious and risky commercialization process governed mainly by the FDA. Uncertainty regarding time delays in a complicated regulatory process causes a financial burden on companies, consequently limiting their investment decisions.[60] Current innovations' sheer pace, volume, and complexity could overwhelm the agencies' existing regulatory capacity.

Section 6 - THE EFFECTS OF BIOTECHNOLOGY ON STRATEGY AND POLICY

"Current national strategies encourage policymakers to view advances in biology through a narrow lens" -- Diane DiEuliis[61]

Biotech promises excellent technological advancement that will shape the future of medicine and human performance. Some concepts presented within this report may seem farfetched, but the threat of its proliferation is very real. Advancements in bioengineering have profound economic and strategic impacts, further heightening its attractiveness and the motivation of nations to attain and expand biotech capabilities. The technological byproducts of the biotech industry are also subject to malign use by persistent and great-power competitors.

China's aggressive plans to dominate the biotech industry exemplify a state's determination and ability to arm themselves with advanced capabilities if they desire. As biotech research continues to unlock more keys to genetic manipulation, Washington must arm itself with the capacity to understand, control, and potentially counter threats associated with

revolutionary sciences. Openness within the international and domestic scientific community enables access to scientific material, data, and equipment that make counter-proliferation efforts difficult. Therefore, educating the scientific community on the perils of the malicious use of biotechnology may prevent or deter their use.

Other than the U.S., Israel is the only other country with governing regulations on conducting dual-use research and the management of high-risk pathogens. China is currently developing better regulatory controls, which they plan to release to the global community for review as an act of cooperation.[62] Further research into country-based policies is required to establish and ensure the success of a cohesive international framework.

The 2018 National Biodefense Strategy meant to culminate disparate efforts across federal services. The Department of Health and Human Services is named the lead with the DOD in a supporting role. Additionally, the Army followed up with its biodefense strategy in 2021, heavily focused on maintaining mobility and readiness in multi-domain operations (MDO) and large-scale combat operations (LSCO).

The U.S. government's response to planning and preparing its biodefense posture requires continual updates as new threats and vulnerabilities evolve. This must include improved and enforced data integration and sharing across the services and government agencies. Further, it consists of an integrated mix of service members, engineers, scientists, lawmakers, etc., to create the most influential and effective strategies. As with all strategies, the government must determine the measure of success. The Biodefense Steering Committee (BSC) must produce standards to gauge compliance and implement innovative ideas.

Future security relies on collaborative interagency and public-private partnerships to develop and implement policy initiatives and enduring international cooperation to stay abreast

of scientific innovations. Both are imperative to the effective regulation of foreign and domestic bioresearch programs and the development of coherent national response programs.[63]

Section 7 – BIOTECHNOLOGY NATIONAL SECURITY STRATEGIC RECOMMENDATIONS

Biotechnology continues to introduce innovations and breakthrough discoveries that improve human life. The battle for dominance in the sector is akin to a modern-day space race like the Americans and Soviets during the Cold War, with China as today's main rival. One of the biggest tests for the U.S. in the next decade will be finding ways to enable this sector's commercial growth and enjoy its economic impact while ensuring they do not run counter to national security priorities. The U.S. can accomplish this by implementing recommendations of a triple helix framework introduced in Section 2a that gives proportionate focus and support to the strands of government, industry, and academia / human capital development.

Strategic Recommendations for Government and Department of Defense

With the U.S. at an inflection point regarding its biotech future, the government should convene a Solarium Commission to find ways to build synergy between public agencies, the private sector, and academia. It must fundamentally address an emerging industry with marked impacts on domestic prosperity and security. This would be similar to the cyberspace solarium chartered in FY2019. The commission must establish a National Bioeconomy Roadmap to facilitate and encourage innovation in the biotechnology field.

This strategy should define industry norms and expected codes of conduct while addressing potential security concerns. This type of public strategy promotes transparency within the government and builds trust with the public. Importantly, this roadmap would establish

priorities, deconflict redundancy, and provide guidance to drive innovation across all sectors.[64] A coordinated national biotechnology road map is a public declaration that the bioeconomy is a national priority and affirms the U.S. position as the leader in the global biotech industry.

Moreover, to be effective in technological developments and scientific uncertainty, the U.S. regulatory system for biotechnology must be flexible, responsive to scientific discovery, transparent, and risk management focused.[65] The U.S. regulatory scheme should be simplified while strengthening oversight by designating a single agency as the regulatory lead assigned by category: plant, animal, or microbe. Under this recommendation, agencies would leverage existing experience and expertise to maintain health and safety while addressing environmental concerns and streamlining new product approval processes.

Further, the U.S. must change the acquisition culture to be more risk-tolerant and let biotechnology innovation flourish while removing excessive opportunities in the regulatory process for bureaucracy to impede progress. It must accept the risk to increase funding for R&D in biotechnology, although there may not be a defined requirement. Lastly, the DOD must allow science and technology innovation to thrive and then determine how to best leverage that to support the warfighter and the mission. The Pentagon should utilize capitalist market forces and allow biotech companies to follow their proven best practices while developing an innovative and business-minded relationship with the biotech industry.[66]

Strategic Recommendations for Private Industry

In a highly commercialized U.S. economy, the government has limited ways to direct private industry to comport to its strategic objectives highlighted above. However, several key initiatives can incentivize and strengthen public-private partnerships to improve the overall national standing in the global biotechnology competition.

The development of biotechnology clusters, and a high concentration of partners within a geographical location, have been essential in achieving the highest global levels of biotechnology innovation and competition. To take full advantage of the U.S. potential in biotechnology and capitalize on the advancements realized, a seismic shift must occur in the way policymakers approach funding and regulating biosciences and biomanufacturing.

The second recommendation is to shore up the cyber infrastructure that underpins the entire industry. The great biotechnology successes achieved thus far, such as the HGP and CRISPR, are a direct credit to the 21st-century digital revolution and advancements in computing. The open nature of the internet and inter-connected technologies allow for information to be widely shared and data to be bulk processed and exploited. Moreover, the globalized nature of the bioeconomy means that data and information must be shared widely internationally. To safeguard against this risk, the U.S. must fortify public *and* private cyber infrastructure according to the National Institute of Standards and Technology benchmarks. The Department of Homeland Security Cybersecurity and Information Security Agency established comprehensive best practices for all sectors to safeguard data, intellectual property, and proprietary information that must be strictly followed. An example is hiring and fully empowering Chief Information Security Officers, which not all private companies employ, to oversee networks and ensure that they are fortified. Potential vulnerabilities should be routinely scanned and patched on time. Publicly traded companies are loathed to work with government agencies and even report a cyber intrusion on their network due to the negative impact on their public stock value. This common practice must end if there is any hope for change and safeguard against these constant threats.

The biotechnology industry should pursue educational investments that widen the human capital pipeline. These programs need to create on-ramps for those who don't have access to or exposure to biotechnology below the high school level. The industry should also consider creating more biotech competitions like iGEM (International Genetically Engineered Machine) to attract young learners. The White House Office of Science and Technology Policy (OSTP) should partner with leading biotechnology industries to develop a biotechnology public awareness campaign. This will include all sectors of the bioeconomy and highlight the growing contribution the bioeconomy has to our nation.

Lastly, the U.S. should incentivize private supply chain management through tax breaks and subsidies. Congress should consider expanding the Defense Production Act (DPA) to incentivize the nation's closest partners. The DPA offers additional flexibility, so the President has the resources and authority to boost domestic production in the interest of national security. The USG must consider longer-term financial incentives to encourage Defense Industrial Base firms and contractors to commit additional resources to enhance resiliency while reinforcing national security. Since the market drives innovation much more than the government, specially designated public-private partnerships are critical to shaping the industry and the nation’s stake in claiming comparative advantages against strategic rivals.

Strategic Recommendations for Academia and Human Capital Development

The U.S. biotechnology industry needs to increase its human capital talent to maintain its competitive advantage and back the overhaul of restrictive immigration policies. The U.S. needs to increase immigration to 1.6 million per year for the next 35 years to ensure increases in the GDP, size of the U.S. economy, and employment growth.[67] The U.S. government needs to consider modifying immigration programs such as canceling limits on H1-B visas and legal

permanent resident (i.e., green card) status since they are administered arbitrarily and stifle STEM development.

The U.S. must also invest in STEM education at the grade school level and not wait for students to take an interest in high school because it is too late by then. They should also assist promising biotech projects with grant funding to seed their development. The technology and its associated intellectual property must remain domestic and not be lost to competitors like India or China.

The U.S. should leverage the Russia/Ukraine conflict. There is an opportunity for the industry to sponsor highly educated and skilled Russians for H1-B visas and green cards. Russia has historically produced a high number of STEM graduates that could immediately be used to support the U.S. biotechnology sector.

Lastly, the U.S. Department of Education must work with the leading biotechnology industry and universities to develop college-level interdisciplinary curricula supporting biotechnology studies. One focus should include integrating biology with other science disciplines, engineering, computing, information sciences, ethics, and other degree programs in realistic environments that will better prepare students for biotechnology careers.

In closing, the U.S. has the luxury of determining its fate in how it will respond to the numerous challenges of contending in the global biotechnology competition. This is because of its vast financial and infrastructure resources and the world's premier academic, technology, research, and development sectors. However, critical decisions must soon be made about the proper organization, funding, and security posture to remain in that top role. Adhering to the recommendations made in this paper will adequately position the U.S. to maintain a leadership role in a dynamic competition, particularly against a Chinese rival that is willing to cut ethical

corners and leverage enormous economic pressure to achieve its strategic goals. By appropriately prioritizing biotechnology's importance and effectively coordinating public and private sector efforts, America can stay ahead in this modern-day space race to improve - and more importantly, not to jeopardize - human life.

Appendix A: Ukraine's Biotech industry

Biotechnology is a significant and strategic pillar in the fourth industrial revolution. The current war in Ukraine highlights three major biotechnology sectors, fuel, food, and medicine. A common need for these sectors and where the U.S. can have an immediate impact is human capital. The U.S. can immediately impact and weaken Russia by enabling rational Russian professionals, specifically scientists, and engineers, to safe and speedy immigration to America. Although the Russian government is pushing its national unity message, a recent poll found about 20% of Russians do not support this war and would possibly choose to support peaceful projects for all humanity. In early March 2022, the British Broadcasting Corporation estimated that 200,000 Russian professionals had left the country. Still, with U.S. and NATO allies closing airspace to Russian flights, many people are moving to other countries.[68] President Biden has proposed a recruitment strategy that must be funded and executed.[69] The exodus of experts will damage the Russian economy. Bringing those experts to the U.S. will provide American companies with additional S&T talent. Further, this program may also increase American biotech expertise in the ongoing competition with China.[70]

Specific to Russia's war with Ukraine, fuel is the most relevant sector of the biotech industry. President Putin manipulated Europe's dependence on its oil and gas as leverage against crippling sanctions. Before the invasion, the European Union (E.U.) imported over 40 percent of its gas from Russia, providing Putin upwards of $118 million a day.[71,72] The NATO countries of Germany and Italy are the leading importers, with Turkey, Netherlands, Hungary, and Poland also in the top seven.[73] Additionally, Russia supplies about 30 percent of Europe's coal.[74] Although economic sanctions have increased significantly since the invasion, a lack of sanctions deterring the aggression enabled Russia to position its forces on the borders of Ukraine freely.

Some NATO and allied nations continue to buy oil, gas, or coal from Russia. Ten days into the war, the U.S. banned all Russian oil, gas, and coal importation.[75] The United Kingdom has started to reduce its reliance on Russia and has pledged to phase out all Russian oil by the end of the year.[76] After the invasion, the E.U. professed its intent to reduce gas imports from Russia as soon as possible to end reliance on all Russian fossil fuels by 2030.[77] Sadly, Germany, Hungary, Slovakia, Austria, and Italy are still paying the Russians for fuel. Poland and Bulgaria have been denied Russian fuel because they cannot meet the demand to pay in Russian rubles.[78] While sanctions have slowed Russian exports, the increased fuel price has not significantly cut Russian profits.[79] The ability of Ukraine to fight Russia to a stalemate into the spring is making it easier for Europe to identify other options for next winter.

Biofuels are a reality, and though they support the global fight against climate change, they are currently not scalable, or profitable enough to capture the international fuel market. The rising cost of fossil fuels has reinforced the push toward going "green" and bioenergy. President Biden notes this with his statement on banning Russian fuel imports, and the E.U. specifically calls out the need for increased E.U. production of biomethane as a greener option to Russian fuel. [80,81] The U.S. consumed almost 135 billion gallons of finished motor gasoline and just over 15 billion gallons of biofuels in 2021 on land transportation alone.[82] The Bioenergy Technologies Office is responsible for managing the growth of the bioenergy sector of America's bioeconomy.[83] They reported that $98 million and $67 million were budgeted for bioenergy opportunities in FY 2021 and FY 2022, respectively.[84] These budgets are woefully underfunded and do not reflect the intent of President Biden. Russia is earning $118 million/day selling fossil fuels to Europe. They use these profits to disrupt the world economy while destroying millions of dollars in American military and humanitarian aid to Ukraine. The U.S. has not met its biofuel

goals set in the Energy Independence and Security Act (EISA) of 2007. Instead of achieving the desired annual production of 36 billion gallons by 2022, reality finds only 15.4 billion gallons produced in 2021.[85,86] The EISA promotes the use of cellulosic for biofuel as it requires less energy to produce than corn or sugarcane biofuels.[87] The U.S. government needs to create strong public-private partnerships (PPP) to link national laboratories, universities, and large American fuel companies to accelerate the inevitable transition to biofuels. Ideally, creating a few PPPs in the biofuel arena would use the American competitive tradition to advance this technology.

Although finding alternative energy options is essential to reducing funding of the Russian war machine, global food security is another issue directly impacted by this war. Ukraine is a major supplier of corn, sunflower seed, wheat, rapeseed, barley, and sunflower meal, with the E.U., China, India, Egypt, and Turkey, its largest consumers.[88] Seventy percent of Ukraine is agricultural land. Further, Ukraine is the world leader in sunflower oil production.[89] Ukraine and Russia provide around 30 percent of the world's wheat. Ukraine provides a significant amount of this wheat, other cereal crops, and cooking oil to the United Nations World Food Programme (WFP) annually.[90,91] While this war has created a food crisis for Ukraine, it has also affected 117 impoverished countries in Africa, Asia, the Middle East, and South America.[92] The WFP estimates the loss of these crops and the increased fuel and shipping costs will add $71 million a month to current WFP costs.[93] Bioagriculture has the potential to change food security for the world dramatically, and the United States has the lead.[94] A significant majority of American corn and soybeans are genetically modified to limit crop disease and reduce the number of chemicals needed for cultivation.[95] These agricultural advances exhibit the ability to create robust crops that make cultivation more efficient and reduce toxicity and waste by creating crops that require less fertilization and pesticides.

Additionally, the continued development of this technology can support crop cultivation in areas not currently feasible for crops. A significant challenge in this field is education concerning agriculture and genetically modified crops. Many European nations do not allow genetically modified crops, including 19 E.U. nations.[96] American leadership must champion collaboration with allies to identify areas of cooperation within the agriculture field. These relationships would offer alternatives in the global push for food security. Further, these relationships, combined with PPPs, can accelerate agricultural advancements. Additionally, improved agriculture supports greener cultivation in the fight against climate change. Finally, these efforts will reduce the overall funding America provides to the WFP and other assistance programs due to agriculture efficiencies.

Biomedicine is an additional biotechnology sector impacted by this war. Economic sanctions did not limit the movement of medical treatments to the people of Russia, reinforcing America's humanitarian reputation. The conflict in Ukraine impacted biomedicine due to a slowdown in data collection for almost 400 clinical trials that were active in Ukraine, many of which were managed by American pharmaceutical companies like Merck, Pfizer, and the medical studies coordination company Cromos. [97,98]

Biomedicine has paved the way for American successes, such as the recent COVID-19 vaccine. The leadership of the government, in coordination with the private sector, demonstrated a successful game plan that can be duplicated for the coming medical and food crisis because of this war. America's lead against COVID, especially the humanitarian distribution of vaccines, strengthened America's international reputation. The U.S. must lead the international effort in support of Ukraine and continued leadership through this type of humanitarian effort, especially with food, medicines, and fuel will support sustained allied resolve against Russia.

Appendix B: China's Biotechnology Industry and Innovation

"The Department will act urgently to sustain and strengthen deterrence, with the People's Republic of China (PRC) as our most consequential strategic competitor and the pacing challenge for the Department." – 2022 National Defense Strategy

Biotechnology is evolving at a fast pace and China's biopharmaceuticals are growing exponentially and only second to the U.S. in the world. China has become the U.S.' main competitor on the global stage in many sectors, including several aspects of biotech. Biotech has always been important in China due to its exceptional biodiversity, a deep culture of traditional medicine, and the perennial need to enhance agricultural production to feed a huge population.[99] However, it has remained rudimentary well into the 20th century, with occasional spikes of brilliance like the complete synthesis of bovine insulin by Chinese scientists in 1958.[100] The sector gained more prominence in the 1980s when genetic engineering was listed for the first time in the 6th iteration of the government's Five-Year Plan (1981-1985).[101] Subsequent Five-Year Plans mentioned biotech, but without a clear vision or a roadmap for its implementation. The true revolution in this sector started in 2010 when the government designated it as a strategic sector. Since then, government policies and targeted investments have led to exponential growth, producing the country's first Nobel Prize winner in medicine, as well as other achievements which confirm China's status as a biotech powerhouse.[102]

In 2020 China's biotech sector was valued at $23.2 billion, representing about 0.13 percent of the national Gross Domestic Product (GDP).[103] By comparison during the same fiscal year, the U.S. biotech sector was valued at $208.2 billion, about 9 times more than China's. Even in the Asia-Pacific region, China's share of the biotech market was only 13.5 percent in 2020, trailing behind India (40.7 percent) and Japan (24.8 percent). [104,105] While these figures represent

the overall status of the biotech sector, they do not tell the whole story. There are areas within the sector, like biopharmaceuticals, where China has leaped above its regional competitors to become one of the forerunners on the world stage. It is the world's leading producer of antibiotics and vitamins, and also a major supplier of Active Pharmaceutical Ingredients (API) and vaccines.[106,107] Innovative drugs in the Chinese market are generally produced by foreign companies, but Chinese companies own the generics market in China and, along with India, lead the world in the production of generics.[108] Through government policies aimed at accelerating the processes of registration and approval, these local companies have drastically reduced the time lag between the appearance of an innovative drug and the production of a biosimilar or low-cost generic.[109]

The COVID-19 pandemic slowed down economies worldwide but was a boost for China's biotech SECTOR. China was the first producer of covid diagnostic kits and has remained a major exporter through the pandemic. It is also the main producer and exporter of Personal Protective Equipment (PPE) which health personnel depend on while operating on the frontlines of medical care. Of great significance too was China's early development of the *SINOVAC* vaccine, which received the World Health Organization's (WHO) approval for distribution to poorer countries.[110] Other success stories of China's biotech include leading research in genetic engineering, especially concerning the CRISPR-Cas9 technology, as well as the increasingly strong value of Chinese biotech companies in international stock markets. [111,112]

Growth in China's biotech sector is irreversible. It might have been helped by the COVID-19 pandemic, but the upward trend was evident well before that and was underpinned by strong government support and control. The continuous recognition of biotech as a strategic sector in the government's Five-Year Plans is testimony to China's ambition of overtaking the

U.S. in the long term. Although it is still behind, the gap is closing especially in innovation and ethics, as more and more Western-trained scientists return home to China.[113]

China will continue to exploit evolving technologies to improve bioengineering and bioscience data collection as a way of attaining supremacy in biotech.[114] Bioscience data, coupled with demographics, would improve personalized healthcare. Less benignly, this could facilitate population control within China, and provide it with priceless information on enemy forces' vulnerabilities. For that to happen, China will continue to grow its gene banks and subtly seek to have access to personal healthcare data worldwide.

Analysis of China's Biotech Sector

Strengths

China's greatest achievement in biotech so far has been to develop self-reliance in many areas and to leverage the West to cover its recognized gaps. Its main strengths are:

- Five-Year Plans: cumulatively, these plans provide a long-term roadmap for success and serve to focus attention and resources on this sector.
- Great supply of qualified personnel: with so many Western-trained returnees and government policy to bolster home-grown STEM talent, there will not be a shortage of qualified personnel in the foreseeable future.
- Cheap manufacturing: low costs have attracted the best international biotech firms to China, and their presence there is helping train Chinese in corporate management, quality control, and drug development, among other things.

Weaknesses

Despite great improvements, China still lags behind the U.S. due to the following:

- Struggle with innovation: Heavy government investment in the past 30 years has not yet succeeded in filling the innovation gap. Innovative therapies generally come from Western firms, while Chinese firms remain fast followers.[115]

- Weak ethical framework: Before the gene-edited babies by He Jiankui, mentioned in the introduction, there was the cloning of macaque monkeys and the proposal by Dr. Ren Xiaoping to transplant a human head onto a different body.[116] Though He Jiankui served jail time and the government subsequently passed many restrictive laws, there is still uncertainty as to how far China could push the science to gain an advantage in its competition with the West.[117]

- Private funding: great strides have been made in recent years, but China is still far behind the U.S. in this category, with only about $60 billion in annual investment compared to $212 billion for the U.S.[118]

- Inadequate quality controls: there have been several instances when Chinese-made healthcare products were withdrawn from the market after they were found to be contaminated and harmful to consumers.[119] Such incidents undermine the reliability of the concerned Chinese firms, but overall, it is China's reputation in the industry that suffers the most.

Conclusion

China's dual-use policy presents a significant threat to U.S. National Security. Dual use technologies that are being developed to improve healthcare could be exploited by China to develop bioweapons. Specifically, China is playing a leading role in developing gene-editing techniques and has one of the world's biggest genetic banks, which happens to include U.S. data.[120] If additionally, China manages to gain access to personal healthcare data in the U.S., it could in a conflict situation develop targeted bioweapons specifically harmful to U.S. personnel. China could also use innovative technology to enhance the performance of its fighting force.

China and the US are not the only innovators in Biotechnology. Refer to appendix A and C for more information about Ukraine and Russia, respectively.

Appendix C: Russia's Biotechnology Industry

Due to Russia's economic sanctions, they have invested in biotechnology agricultural applications. Russia is not competitive in biopharmaceuticals and its entire biotech sector is ranked among the worst of developed nations. The Russian Federation is lagging far behind world leaders in biotech. Unlike China which started from nothing, Russia has seen its biotech sector go from number two in the world, down close to extinction, and then in the past 12 years, struggling to rise again.[121] Biotech revival in Russia began in 2010, spurred by government regulation and funding, like China's, though with less satisfactory results. The defining aspect of Russia's biotech sector today is the dominance of agriculture, whereas world trends are largely in favor of biomedicine and human health.

Today Russia is the world's biggest producer of grains and continues to excel in leveraging technology to improve the quality and quantity of agricultural produce. As technology develops, the government continuously provides direction and sets boundaries; an example is the 2016 banning of Genetically Modified Organisms (GMOs) from the Russian market.[122]

Despite the strength of its bio-agriculture, Russia's biotech sector ranks poorly in the world. In a 2022 study conducted on 54 countries by *Scientific American Worldview*, Russia ranked 44th, lodged between Mexico and Thailand.[123] Of the six categories considered in the study, Russia's lowest scores came in "Intellectual Property protection" and "Policy and Stability", both of which have a heavy influence on innovation.

Lack of innovation and funding has been the main pitfalls of biopharmaceuticals in Russia, a market shaped by large foreign firms, but in which small local firms are playing an ever-increasing role.[124] Steady growth in this market has been fueled by expanding demand from an aging population with a high incidence of pulmonary and cardiovascular diseases. Since the demise of the Soviet Union, Russia has been a net importer of pharmaceutical products, but efforts have been made in recent years to reverse the trend through the state's "Pharma 2020 Plan".[125] The implementation of this plan has shown some remarkable results, with pharmaceutical exports increasing by 6.2 percent in 2019 to reach an unprecedented total value of $843.8 million.[126] By comparison, U.S. pharmaceutical exports during the same year were valued at $60.2 billion, about 71 times more.[127]

To overcome its inability to compete with major biotech countries like the U.S., Russia rushed to be the first to produce a vaccine against the COVID-19 virus, authorizing the use of *Sputnik V* even before the completion of its phase III clinical trials.[128] Though a recent study conducted in Italy suggests that the *Sputnik V* is more effective than two doses of the Pfizer-BioNTech mRNA vaccine, the WHO would not approve *Sputnik V* without conducting its investigations. Approval by the WHO would lead to *Sputnik V*'s enrollment in the COVAX program which aims at buying vaccines and donating them to poorer countries. This would increase Russia's prestige on the world stage and more importantly, it would rake in huge revenues to prop up the struggling biopharmaceutical sector. Unfortunately, WHO investigations were suspended indefinitely after Russia invaded Ukraine.[129]

Future Trends

Apart from bio-agriculture, other segments of the biotech sector are finding it hard to compete. Any signs of growth they showed before will be annulled by the overbearing sanctions

imposed on Russia after it invaded Ukraine. These new sanctions, coupled with those imposed in 2014 after the invasion of Crimea, would push the entire Russian economy back several years. In this context, it is hard to predict a bright future for biotech in Russia.

Analysis of Russia's Biotech Sector

Strengths

Despite unfavorable current conditions, Russia's biotech sector has the potential to be a big player on the world stage, because of the following factors:

- Government's will to develop the sector: as demonstrated by recent legislative actions and the bold move with *Sputnik V,* the government recognizes the importance of biotech to national security and economic development. Its continuous commitment would be essential to the development of the sector when international sanctions end.
- Great biodiversity: arable lands, huge forest reserves and plenty of fresh water sources are critical resources at Russia's disposal.
- Huge internal demand for biotech products: whether it be for bio-agriculture or biopharmaceuticals, there are many unmet needs within Russia, making it an attractive biotech market.

Weaknesses

Unlike China, Russia has not been able to tap from the world biotech ecosystem to improve its own. A rough political transition from the Soviet era and recent sanctions can be blamed for its main weakness, which is the lack of innovation. Tied to this problem is the very low availability of R&D funding from both the public and private sectors.

Appendix D: U.S. Biotechnology Industrial Base SWOT Analysis

Strengths

1) Quantity and access to R&D capital: In 2021, U.S R&D expenditures totaled $384 billion. These expenditures represent the total funds spent by companies or the federal government on research and development performed in the U.S. US R&D expenditures are forecasted to grow at an annual rate of 2.98 percent through 2027.[130] Numerous venture capital and angel investment opportunities exist within the biotechnology ecosystem.
2) U.S. soft infrastructure: intangible components like the entrepreneurial culture, educational system, investors, and firms offering the business and legal skills needed for success. A key part of the soft infrastructure is the nexus of business laws and regulations, intellectual property protections, effective courts, and capital markets. Soft infrastructure minimizes the risk for entrepreneurs as they turn research into innovations and provides advantages over competitors.[131]
3) Partnerships and ability to develop coalitions for the bioeconomy, biosecurity, and protection of biodata.

Weaknesses

1) Public awareness of the bioeconomy and its future impacts on the U.S. economy and the American way of life.
2) Federal rules and regulations that govern government acquisitions could be an obstacle to linking national security access to innovative technologies.[132]
3) Commercial innovation connection to national security: It needs to move faster and improve in quantity and timeliness.[133]

4) The cultural mismatch between traditional acquisition and risk acceptance: The defense acquisitions process was designed to manage the twentieth century's complex, expensive weapons programs. It is perhaps the best in the world at this task, but it is reluctant to take risks associated with innovation in biotech.[134]
5) U.S. Government's narrow view of biotechnology: The vital role of biotechnology in military readiness and national security remains poorly understood. Biowarfare and bioterrorism are real risks but approaching the nation's biotechnology security needs only in these terms will leave the country ever more vulnerable.[135]

Opportunities

1) The coronavirus global pandemic generated greater flexibility to partner with American innovators and entrepreneurs and new partnerships with allies in Europe and Asia.
2) Co-development of biotechnology education and training programs with allies and partners.
3) Aging U.S. population: A higher share of the population with severe health conditions spurs public and private spending on activities that aim to prevent disease and promote health and wellness. Total health expenditure is expected to rise in 2022.[136]

Threats

1) Human Capital: While the U.S. remains preeminent in scientific education and research, it has reduced the number of its citizens being educated and does not aggressively seek to retain enough of the scientific talent it graduates. In effect, the U.S. has reversed the workforce policies that gave it a technological advantage for 50 years.[137]
2) Intellectual property theft.

3) Supply Chain dependency on China: Over the last two decades, biotechnology has become a key component of American supply chains, perhaps accounting for 20 percent of the U.S. military's chemicals. Those supply chains now span the globe and contain a significant amount of material produced in China. Remarkably, the full extent of the military's dependence on Chinese biotechnology is unknown because the U.S. government is not assessing it. These dependencies extend beyond pharmaceuticals to fundamentals such as solvents and polymers.[138]

Appendix E: BIOTECH AND HUMAN PERFORMANCE OPTIMIZATION

Human enhancement is a subject that has been in the vernacular of the DoD for decades. However, most of the efforts seek corrective chemical therapeutic means to protect the force without the necessary deeper understanding of the physiological and neurological aspects of the human organism. This trend is also evident in the civilian sector when considering that the supplement industry is now worth an estimated $40 billion without the requirement of proven effectiveness through the Federal Drug Administration (FDA)."[139] This indicates that the federal government and civilian sector lacks efforts and funding in basic research to understand better the brain's neurological functions or the digestive system.

There will be substantial advancements in human enhancement over the next 30 years. The U.S. and its allies must be at the forefront of this science. To ensure this is done safely, effectively, and efficiently, the federal government's department of defense and other interagency partners needs to focus more resources on basic research of the brain and the digestive system.

Since the beginning of human civilization, the desire for physiological improvements in the mind and body has been a subject of interest. This desire, however, was only achievable

through naturally available means such as exercise or dedicated study. In the contemporary environment, "Human performance enhancement can be interpreted as an implantable, ingestible, wearable invasive, or non-invasive technology that can temporarily or permanently change or promote human function."[140] The technological advancements in computer technology, pharmaceuticals, and bioengineering have taken what was predominantly used to treat human ailments or defects and have opened the door to advancing healthy individuals' physical and cognitive capabilities. The future will include "the convergence of synthetic biology and materials science and engineering, leading to technologies in which living organisms are part of the materials used by the warfighter for enhanced performance, sensory augmentation, protection, or situational awareness."[141]

This continued advancement will require a significant understanding of the interworking of both the human's physiological and cerebral functions to use Human Performance Enhanced Technology (HPET) safely and effectively. Basic scientific research on the human brain and body will be vital to advancing HPETand will be necessary for the great power competition, predominantly against China. The U.S. and its allies will need to lead the exponential increase of understanding of the body and mind and how to integrate computer technology, known as Brain-Computer-Interface (BCI). This is the next evolutionary step of Moore's law which is now expressed as a "law of accelerating returns" vice the doubling of transistors on integrated circuits every two years as initially described in 1965 by Intel CEO Gordon Moore. This understanding will require effective data management, including artificial intelligence that will provide the necessary knowledge management to transition to the applied science of HPET.

There is a high risk to national security if the U.S. does not maintain the leading edge or keep pace with great power peers in HPET. Historically, peer competitors like China and Russia

have not been hindered by ethics, and authoritarian governments are not likely to be slowed down by regulations. HPET is of vital interest, and if not prioritized, the U.S. intellectual/technological capability advantage will be overwhelmed by peer competitors who accelerate enhancement in BCI, senses, and other human physiological functions. The greatest challenge the U.S. and DOD will face is the regulatory and ethical (primarily religiously driven) challenges inherent in its democracy. The DOD will have to be allowed to take risks in this space.

Appendix F - Acronyms and References

Acronym	Definition
A.I.	Artificial Intelligence
AMEDD	Army Medical Department
BSC	Biodefense Steering Committee
CAR-T	Chimeric Antigen Receptor Tissue
CFIUS	Committee On Foreign Investments In the United States
COVID	Coronavirus Disease
CPT	Curricular Practical Training
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DAS	Defense Acquisition System
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DPA	Defense Production Act
FDA	Food And Drug Administration
GDP	Gross Domestic Product
HGP	Human Genome Project
iGEM	Internationally Genetically Engineered Machine
LPR	Lawful Permanent Residence
LSCO	Large-Scale Combat Operations
MDO	Multi-Domain Operations
mRNA	Messenger Ribonucleic Acid
NIH	National Institute of Health
NTIB	National Technology Industrial Base
OPT	Optional Practical Training
OSTP	Office Of Science and Technology Policy
S&T	Science and Technology
R&D	Research And Development
STEM	Science, Technology, Engineering, And Mathematics
SynBio	Synthetic Biology
TRL	Technology Readiness Levels
WTO	World Trade Organization

Appendix G: Research Methodology

This group paper is the result of fifteen weeks of study, over forty field study engagements, and seventeen individual papers. Field study engagements were all non-attribution and included discussions with the government, academia, and industry. Understanding of this complex topic was further informed by the parallel studies of Industry Analysis. While the class focused on Biotech in healthcare, the class also explored biosecurity and industrial biotech. Below is a breakout of the individual papers used to formulate this group analysis:

LTC Robert Brutcher, United States Army: "DoD Acquisition and Procurement of Biotechnology: The Leader of Biotechnology and Innovation."

Col Christina Buchner, United States Army: " Gene-Editing Technology: Striking the Balance Between Policy and Ethics to Achieve Strategic Advantage."

Col Mindy Davitch, United States Air Force: "Human Capital in Biotech."

Mr. Gerald Davitch, Federal Bureau of Investigation: "Biosecurity and the Double-Edged Sword of Synthetic Biology."

LTC Tammy Fearnow, United States Army: "Regulation, Innovation, and the Bioeconomy – How the U.S. Remains the Global Leader in Biotechnology"

Ms. Jennifer Fletcher, Department of the Air Force: "Beyond COVID and Biopharma: Biotechnology Defense Industry and the Defense Industrial Base."

Mr. Thomas Gallagher, Department of the Navy: "The US Innovation Base in Biotechnology."

Mr. Greg Grunwald, Department of the Navy: "Biotechnology: Human Performance Enhancement."

LtCol Nicholas Lozar, United States Marine Corps: "Biotechnology Industry Challenges: Intellectual Property, Patents, and Technology Transfer."

CDR Sean McCarthy, United States Navy: "US Trade Policy for Biotechnology."

LTC Andra Moore, United States Army: "Bioethics and National Security"

Lt Col Michael Murphy, United States Air Force: "The State of Biotech for Germany and Brazil."

CDR John Olabode, United States Navy: "Investment and Funding in Biotechnology: A National Security Imperative."

Col James Pryor, United States Marine Corps: "Biotechnology: Disruptive Technology and US National Security in the 21st Century."

COL Jean-Francois Simard, Canadian Army: "Supply Chains and Biotechnology: A Matter of National Security"

CAPT Emmanuel Stone, Cameroon Navy: "Current and Future State Biotech: China and Russia."

Ms. Elanor Winchester, Department of the Army: "DoD's Strategic Approach to Biodefense."

This paper was further informed by the guidance and leadership of the following Eisenhower instructors and faculty:

COL Jeffrey Thomas	United States Army
CAPT Thomas Welsh	United States Navy
Dr. Robert S. Brent	National Defense University
Col Eric Murphy	United States Air Force
Dr. Nicole Crain	National Defense University

APPENDIX H: Industry Analysis Firm Briefs

Refer to separate file for 5 industry analysis firm briefs.

ENDNOTES

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