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BIOTECHNOLOGY – HOW THE UNITED STATES CAN MITIGATE RISKS AND INCREASE OPPORTUNITIES FOR THE NEXT INDUSTRIAL REVOLUTION.

INDUSTRY STUDIES GROUP PAPER

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Like the previous industrial revolutions in chemistry and engineering, the era of biotechnology is swiftly altering human progress and the global landscape. The biotech industry is rapidly changing how humans create food, acquire resources, and approach healthcare – it has the potential to impact every facet of human life. Biotechnology provides tools through which humanity can effectively tackle the adverse consequences of human development, encompassing environmental degradation, climate change, and the inequitable distribution of food supplies. Biotechnology is also presenting society with new challenges, compelling people to confront ethical dilemmas, security threats, and divisions regarding the acceptance or rejection of this rapidly expanding industry.

The breadth and depth of the potential impacts of biotechnology have profound implications for national security. The biotech industry offers viable solutions to address the expected geopolitical instability caused by climate change in the coming decades. The escalating demands on natural resources, including crops, energy, and minerals, pose significant security challenges. However, the biotech industry shows a promising avenue for addressing these challenges and easing the strain on resources. In addition, finding solutions to the increasing healthcare costs and aging population can be addressed by exploring innovative biotech methods for human development, which can also help ensure the safety and security of the United States and our allies. However, the emergence of biotech innovations that provide new avenues to enhance national security gives rise to ethical dilemmas and security considerations. The United States needs to develop its strategy carefully and promptly to stay ahead in the biotech revolution. This paper outlines a few of the many national security issues biotechnology presents. It offers policy recommendations to ensure the U.S. government and other authorities can safely, sustainably, and ethically foster the constructive growth of the biotech industry.

Biotechnology and Our Environment

Although many of humankind's technological advances have degraded the environment, the current innovation revolution in biotechnology can potentially ameliorate, and even reverse, the damage done to the world. By offering novel approaches to creating new biofuels and other sources of energy, reducing anthropogenic carbon emissions, and recapturing the carbon humans have already released into the environment, biotechnology has the potential to address the worst impacts of climate change. The new pathways presented by biotechnology are essential for preserving the environment, public health, and U.S. national security. Climate change is disrupting agriculture and trade, derailing economies, eliminating resources, generating mass migrations, and creating advantages for U.S. competitors. It is arguably the single greatest threat to global security. The United States must prioritize finding solutions to combat climate change. Utilizing both traditional and innovative biotechnology methods may hold the key to achieving this goal.

Societies must tackle climate change and pursue sustainable resources for continued growth to feed an ever-growing population, fuel economic development, and protect the planet that sustains these activities. Nation states must improve resiliency, safety, and accessibility of essential resources such as crops and minerals. Biotechnology offers new ways by which the United States and other countries can safely, sustainably, and equitably produce the food, materials, and energy we need today while ensuring the biodiversity in seeds for tomorrow. Similarly, novel biomining technologies are opening cleaner and more sustainable paths toward extracting the metals and rare earth elements that the modern world needs. By exploring and developing methods that enhance organisms and organic processes, biotechnology

simultaneously presents opportunities to improve human security and environmental sustainability.

Governments at every level in the United States have taken significant steps to support biotechnology solutions by providing research and development funding, loans and loan guarantees, tax incentives, and regulatory mandates to encourage or enforce the adoption of beneficial technologies. However, federal and state governments need to do more to accelerate the use of such technologies, including the passage of consistent regulatory frameworks and increases in financing and incentive tools. The U.S. government also needs to more emphatically engage the American public and global partners to address legitimate and misplaced concerns about biotechnology and encourage solutions that biotechnology can offer for climate change and other societal challenges.

Biofuels, Biomass, and Reducing Petrochemical Requirements

Petrochemicals like coal, crude oil, and natural gas took millions of years to create and are, therefore, not considered renewable resources. The combustion of these fossil fuels releases carbon into the Earth's atmosphere in the form of carbon dioxide, increasing the global average temperature and contributing to climate change. Recent advances in biotechnology, specifically bioenergy, provide an opportunity to harness near zero-carbon and low-carbon methods of producing the same petrochemical fuel, fuel-based products, and energy used today for everyday life. One way to achieve a sustainable shift is by transitioning the transportation sector to electric and bio-based fuels. Another step is to reduce the energy consumption of high-energy industries by replacing traditional processes. Lastly, petrochemical-based electricity generation can transition towards renewable energy sources.

Biofuels like ethanol have been used for many years, but they have faced criticism for pushing the industry towards alternative fuels that still release carbon into the environment. However, corn ethanol emits approximately 30 percent less carbon than gasoline. Soybean-based biodiesels succeed in reducing carbon emissions even further – by up to 40 to 50 percent when measured over the entire life cycle of the fuel.[1] Biotechnology is discovering new ways to reduce the carbon intensity of ethanol and biodiesels, promising to increase the positive impact of substitution fuels in the short and medium run. Since 2009, biofuel use has reduced greenhouse gas (GHG) emissions within the U.S. transportation sector by approximately one billion metric tons of carbon dioxide. This is the equivalent of taking more than 16 million vehicles off the road.[2] Given that track record and the urgency of the climate challenge, policymakers cannot afford to turn away from these alternative fuels. Widespread use of electric vehicles and other alternative energy sources will result in even greater reductions in the coming decades. However, the benefits of biofuels are available and remain an option today.

Biotech is also playing an essential role in the development of new biofuels which promise far lower emission levels. Biotechnologists have enabled ethanol production from grasses, shrubs, and other non-traditional feedstocks by developing biocatalysts and engineered microorganisms. These engineered processes allow the breakdown of plant cellulose and hemicellulose into glucose, creating fuel ethanol. Although this conversion is the same process used for corn glucose, these cellulosic biofuels have a lower carbon density, improved yields, and decreased cost in a broader spectrum of cultivation conditions. If cellulosic biofuels can overcome current technological and supply chain challenges, they may offer 60 to 80 percent lower emissions than conventional fuels.[3]

A third generation of biofuels is even more promising, potentially achieving carbon neutrality. Leading this area of research are efforts to employ algae as biomass to produce carbohydrates at, theoretically, remarkably high yields. Most intriguing is the possibility that algae can be grown using exhaust gas or wastewater, creating a virtuous (re)cycle that creates an energy source from waste that would otherwise further contribute to climate change and other forms of pollution. Algae is also an attractive feedstock due to its high biomass yield and lipid content production rates per acre, as well as being able to be grown on low-value land and with water unsuitable for growing foods and raising crops.[4] Research is underway on algae-based fuels because they can be grown almost anywhere. Different strains work best in different climates and salinity levels. Algae show promise but must overcome technical hurdles for development and scale to supply aviation, ship, and other heavy equipment like cranes and tanks. If algal fuels can eventually be commercialized, they represent the possibility of providing massive quantities of low-carbon biofuels that could be compatible with existing transportation technology.[5]

Biofuel sources for energy can also come from wood and wood processing waste, agriculture crops and their waste materials, biogenic materials found in municipal waste systems like garbage, and animal manure or human sewage. These sources are essential in reducing the world's carbon emissions, but the scale of their contributions is marginal compared to the overall global power requirement. It is worthwhile to continue research in this area, but great efforts should go towards algae research, given the limited financial resources in the algae area of biofuels.

Biomanufacturing

Biomanufacturing, a process that uses biological systems to produce goods and services at a commercial scale, has the potential to drive new sustainable alternatives across the food, fuels, packaging, and pharmaceutical industries.[6] The field of biomanufacturing has the potential to address major challenges related to resource management, climate change, economic sustainability, and environmental equity. By using genetic engineering to create bio-based materials, the United States can decrease its reliance on petrochemicals, synthetic fertilizers, and excessive water usage, leading to a significant reduction in greenhouse gas (GHG) emissions and environmental damage.[7]

The manufacturing of daily-use products such as apparel, plastics, packaging, carpets, and cosmetics is a major GHG emitter, accounting for 22 percent of total GHG emissions in the United States.[8] Using renewable feedstock instead of fossil fuels to create inputs through biotechnology could significantly curtail these global-warming emissions. The employment of new biotechnology tools such as gene editing and synthetic biology can produce bio-based inputs at adequate quantities and acceptable cost and use low-energy intense processes. These tools offer a sustainable model for manufacturing without the attendant high GHG emissions, so high-manufacturing nations such as the United States and China could register significantly lower GHG emissions.[9] Research shows that using enzymes and microbes in biomanufacturing could reduce GHG emissions by at least 80 percent compared to traditional manufacturing processes.[10]

Industries such as cement, steel, and fertilizer manufacturing require a lot of energy to produce their products. This is because they need high temperatures to transform raw materials into the desired product. The production of cement and steel contributes to approximately eight percent of global CO^2 emissions each, while global cement production uses approximately 10

percent of the water available for human consumption. Utilizing biological methods to produce these materials would be a significant step toward reducing CO^2 emissions and mitigating water scarcity.[11] Cement has been developed with naturally occurring bacteria to combine carbon and calcium to produce bio-cement in less than 72 hours.[12] Instead of producing CO^2 as a byproduct in energy-intensive raw material manufacturing at temperatures of 2,400° F, this technique uses carbon as a building block and reduces carbon emissions by 99.4 percent.[13]

As cement is the most consumed substance in the world after water, this reduction in carbon emissions is significant.[14] In addition to growing cement for cement tiles, sidewalks, seawalls, and helicopter landing pads, bio-cement in some applications can be stronger than traditional cement. There is now a method to use biological means to repair cracks in cement, eliminating the need to replace an entire structure. The DoD can utilize this technology in structures like helicopter landing pads, floors, and wall barriers in austere locations. This technology can also be used to mitigate the effects of climate change when used in the construction of seawalls or breakwater devices that minimize beach erosion.

Carbon Capture and Sequestration

While many of the biotechnology advances reviewed thus far will help curb future emissions and slow the acceleration of climate change, stabilizing global temperatures will only be possible with significant progress in removing carbon dioxide from the Earth's atmosphere. In other words, humanity must reduce GHG emissions to zero, reverse the contamination already created, and do so quickly. Human progress will outpace the Earth’s capacity to naturally form underground carbon capture storage systems that convert biomass products like plants, plankton, and animal remnants into petrochemicals such as coal, crude oil, and natural gas. However,

biotechnology can play an essential role by providing multiple carbon capture and sequestration (CCS) tools. The biotechnologies in this area overlap with other technologies, such as biomass, biofuels, and biomanufactured products, due to the reinforcing nature of the methods and outputs involved.

A prime example of such interplay is bioenergy using carbon capture and sequestration (BECCS), which combines the use of biomass from plants to produce fuels or energy while simultaneously storing carbon in the process. One of the most promising methods for reducing carbon emissions is BECCS. This process involves two main technologies: first, generating biomass which absorbs carbon from the atmosphere as it grows, and second, converting this biomass into energy or heat while capturing and storing the resulting emissions in geological formations or in durable products.[15] When implemented properly, BECCS can be a carbon-negative emissions technology that can combat climate change on multiple levels. It can draw down carbon levels from the atmosphere. However, if not done carefully, the growth, harvesting, transportation, and storage of the requisite biomass could outweigh the benefits bestowed by BECCS. One study estimated that BECCS could effectively remove over 700 million metric tons of carbon annually, or more than half the emissions from all U.S. coal power plants.[16] However, reaching that goal will require producing a tremendous quantity of biomass feedstock.

Similar benefits and risks apply to gasification systems that produce biochar, a charcoal-like substance made by burning organic material from agricultural and forestry wastes in a process called pyrolysis.[17] Pyrolysis works by burning organic materials in a controlled space or container with very little oxygen, releasing virtually no emissions and converting the biomass fuel into biochar, a stable form of carbon. Clean energy generates from the heat during the process. In contrast, the resulting biochar can be used as a soil amendment to improve

agricultural productivity.[18] Meanwhile, the entire biochar production process serves as a means by which large quantities of carbon can be sequestered and held in the soil for thousands of years. In fact, by transforming the carbon in the feedstock into a stable carbon that does not react to oxygen, biochar technology can reduce the amount of carbon the feedstock would have released had it been left to decompose naturally.[19]

Biotechnology and Climate Change Policy Recommendations

To better foster the sustainable application of biotechnologies to combat climate change, the U.S. government must develop a long-term U.S. biotechnology strategy that sets priorities for research and development (R&D) investments, workforce development, regulatory framework, and comprehensive monitoring of the bioeconomy. It will also need to work with state governments and other countries to construct consistent domestic and international regulatory frameworks and standards that incentivize biotechnology innovation in the fight against climate change.

For the United States to maintain an edge in biotech innovation, it must significantly expand federal subsidies, grants, loans, and loan guarantees for firms pursuing biotechnological solutions to climate change. Given the expected limitations on such financing tools, the United States should concentrate funding on biological processes which can reduce energy consumption for industries using large amounts of power, starting with the cement, steel, and plastics industries. Funding promising biofuels, such as algae-based fuels, to achieve commercialization should also be a priority. Policymakers can enhance DoD's efforts of creating biomanufacturing hubs in the United States by collaborating with the private sector, non-governmental organizations, and academia. This will help in commercializing innovation from small biotech

start-ups. Maintaining centralized biological capabilities databases managed by the government is the most feasible way to prevent duplication and promote collaboration between the government and the private sector. Access and dissemination of biotech data will promote competition, innovation, and quality of products and help ensure the United States continues to lead the global effort to combat climate change.

Agricultural Productivity and Resilience

A country's ability to feed its people is paramount to national security. Crops are the foundation for most of the world's food supply, including the United States. Since the early twentieth century, biotechnological improvements in crop seed development have significantly increased food availability. However, these advancements have introduced vulnerabilities, including a lack of biodiversity in modern crops and over-dependence on chemical inputs. Many of the crops grown throughout the world are also used as feedstock in the production of animal-based protein. These food sources are increasingly becoming less efficient as populations continue to rise and animal meat becomes more widely available. To ensure our food security in the future, the United States needs to acknowledge and tackle the vulnerabilities created by decreased biodiversity and limited resources.

The U.S. agriculture sector faces additional challenges, including crops susceptible to disease, drought, and overtaxed soils. Biotechnology can address these issues through gene editing and cultivating sustainable food sources to achieve broader national security goals. Policymakers must consider the array of complexities along with biotechnology's tremendous potential. Challenges include a largely privatized agriculture sector subject to industry and market incentive structures that may not align with national security goals. These challenges will

impact the ability of biomanufacturing to scale up in the private market, driving resourcing and manufacturing overseas.

Biotechnology Can Improve Agricultural Resilience

Crop seeds are a critical resource deserving of a status as one of the most cherished treasures on Earth. They are vital to humanity's ability to sustain itself. Grain seeds play an enormous role in feeding the world, and the United States is no exception. Nearly half of all human caloric intake today comes from grains, and the United States significantly contributes to global grain supplies.[20] According to the United Nations Food and Agriculture Organization, the United States is the second largest grain producer in the world, behind only China, producing over 450 million metric tons, representing 15 percent of the worldwide supply.[21] Yet, despite grain's importance, crop seeds are at risk due to limited biodiversity and potential supply chain disruptions. Risks to crop seeds could result in interruptions to the food supply, which could, in turn, erode the public's faith in the future availability of food. Those living below the poverty line would suffer the most, but food shortages would affect everyone’s confidence in the government's ability to provide basic needs and could exacerbate an already tense and polarized domestic political climate. Given these realities, the United States must do more to protect crop seeds if it is to maintain a healthy agriculture industry.

Achieving resilience through biotechnology can be achieved using gene editing in commercial crops. To meet the increasing demands of a new bioeconomy, government agencies will seek to expand the use of the most productive crops, such as corn, soybeans, and wheat. Among these, corn is the most profitable and widely grown crop in the United States. Corn is used domestically and internationally in products like feedstock, high fructose corn syrup, and

ethanol. The United States has experienced significant growth in corn grain yields, which have increased from 8.7 billion bushels in 1997 to 14.8 billion bushels in 2017. During the same period, farms decreased by 41 percent.[22] The reduced number of farms, less arable land, and increased concern about soil quality and water availability has increased the need to accelerate biotechnology to adapt plants to larger farms that may be located in drier climates.

In 1982, scientists developed the first genetically engineered plant, an antibiotic-resistant tobacco plant. Later, in the mid-1990s, genetically modified organism (GMO) foods became available for commercial purchase. With the breakthrough of CRISPR technology in 2012, plant breeders can be even more precise in editing genetic code to add or remove plant traits, limiting the potential for off-target effects. Now the process that used to require many years and thousands of random crosses can now be accomplished in a significantly shorter period.[23] To illustrate the dramatic growth in crop production due to these improvements in agricultural biotechnology, the USDA summarizes:

> Average corn yields rose from 20 bushels per acre in 1930 to 140 bushels per acre by the mid-1990s. Over the same period, cotton yields rose nearly fourfold, soybean yields increased more than threefold, and wheat yields climbed more than 2.5fold. Genetic improvements from plant breeders make up more than half of the yield gains.[24]

GMOs are highly prevalent among the most profitable crops in the United States, particularly corn. Though corn is quite productive, it is also susceptible to drought. Corn is an open pollinator that requires between 22 to 30 inches of water annually, mainly during early reproductive growth.[25] Research in private industry and educational institutions has focused on producing seeds with drought-tolerant traits to sustain yields. Researchers for Monsanto have concentrated on ensuring plants can create the necessary proteins required for continued growth in later stages. Their product, “DroughtGard," introduced in 2013, has been gaining popularity as demand for drought-tolerant crops has increased. This seed is part of a larger class of corn

varieties called "Dt corn," engineered specifically to help plants grow under low water conditions.[26] According to a study by the USDA, these seeds are effective in moderate conditions but still lead to high losses under severe drought conditions.[27] Strong demand in the industry will help drive research for better seeds. However, policymakers should also slow demand for grain such as corn to alleviate risk.

There is a major effort underway to reduce the risk associated with the high demand for crops by producing alternative protein sources that are more sustainable. There is a pressing need to improve efficiency in protein production as global meat demand continues to climb. In the past 50 years, the world's population has doubled, and meat consumption has gone from 70 million tons to 330 million tons.[28] Currently, animal-based meat consumption accounts for 70 percent of freshwater usage and requires 37 percent of all grain production in the United States.[29] Animal-based protein also contributes significantly to deforestation and methane emissions. Chicken, pork, and beef production require substantially more land than plant-based meat alternatives.[30] Furthermore, factory farming faces ethical issues and pandemic risks, making this industry increasingly untenable. Given the increased risks of animal-based protein and the growing promise of newer protein alternatives, the United States should diversify protein supplies for domestic consumption and export.

Because of its enormous potential, the private industry enthusiastically funds research and development of alternative protein sources to address these concerns. This trend is occurring in more than just small start-ups. Many major corporations recognize the trend toward sustainable protein and are undergoing a "protein transformation." In 2019, Tyson Foods, the world's second-largest meat processor, appointed its first-ever head of alternative protein.[31] The scientific community is welcoming these efforts from private industry as many experts predict

that regions such as Europe and North America must reach a "peak meat" milestone over the next decade to meet climate goals.[32]

There are currently several plant-based protein alternatives available in the market, although they only make up a small percentage of the total market. Most of the investment in the private industry is directed towards “cultivated” meat, produced by growing a small sample of animal cells in a nutrient-rich environment. This protein source has the potential to be the most effective substitute for animal-based options. Since the introduction of the first cell-based burger in 2013, there has been fierce competition among companies to create the first commercially available product. Unlike other areas of biotechnology, alternative proteins will need to compete in price with animal-based sources to achieve sufficient market share. Over the past decade, tens of millions of dollars in private sector investment have poured into this technology, intending to reduce costs and scale up the process to compete with animal-based meat.[33] Unfortunately, the current industry is already highly efficient as currently configured, making it challenging to surpass with new technologies.

Biotechnology and Agriculture Policy Recommendations

Modern agricultural biotechnology can play a key role in meeting agriculture's challenges from overreliance on agrochemicals and limited crop biodiversity. Growing GMO crops that perform well and reduce the need for chemical inputs poses a significant potential benefit. Many benefits exist today. According to a summary of peer-reviewed research, GMO crops have lowered chemical pesticide use by 37 percent globally and enhanced crop yields by 22 percent.[34] It is important to note that numerous esteemed institutions, such as the World Health

Organization, the American Medical Association, the U.S. National Academy of Sciences, and the British Royal Society, have all concluded that GMO foods are safe for consumption..[35]

Another promising development is growing research and interest in using sustainable biologics to provide crop nutrition rather than relying on synthetic fertilizers. Agricultural biologics comprise a wide range of products that originate from naturally occurring microorganisms, plant extracts, beneficial insects, or other organic materials.[36] Biologics has the potential to replace reliance on chemical inputs for American farmers. Food producers who avoid using chemicals are more likely to address concerns from consumers who are hesitant to purchase such products. The federal government should seek ways to incentivize investment and competition in these agricultural biotechnology arenas.

GMOs and crop biologics complement other regenerative agricultural practices that can also help reverse the harmful impacts of modern industrialized farming. For example, incentivizing cover crops to amend soils naturally can also improve agricultural resilience and break dependence on synthetic fertilizers. In addition, greater use of pre-modern grains, known as landraces, which developed over millennia to adapt to local environmental conditions, can improve biodiversity amongst American crops. Ensuring a source of genetic variation in grains is essential for disease and pest resistance. Landrace grains are vital in providing diversity, but farmers rarely grow them today given the higher productivity of modern grains. Many landraces were lost during the twentieth century as farmers abandoned them in favor of modern varieties championed in the Green Revolution.[37] Due to their wide genetic diversity, landraces need to possess the genetic bottleneck of modern grain varieties.

To further resiliency, the United States must focus on drought resistance seeds and crops. Though drought-resistant seeds have been on the market for a decade, they still have significant

capability gaps to withstand severe drought. Severe droughts have impacted the western states of the Corn Belt region leading to substantial losses in corn yields despite the use of Dt varieties. With climate change projections showing a gradual shift of high temperatures toward middle and eastern states, crop productivity remains vulnerable. Temperature changes can outpace the ability to improve drought tolerance through conventional breeding techniques. Congress should authorize programs focusing on increased support for research programs that build knowledge about important crop traits to improve them. Farmers can achieve long-term cost savings by reducing crop losses during the growing season by utilizing better seeds and practices. Congress will likely experience a reduction in crop insurance programs over time.

The federal government should also continue to support policy initiatives that reduce agriculture's carbon footprint by supporting continued research in alternative proteins. Consumer trends in the sector show growing demand for new sources, but the current market share is a small fraction of the overall protein market. Private capital in alternative protein has increased substantially over the last decade. Even with funding efforts in place for the protein market, biomanufacturing in this field is still in its early stages. Federal support to expand the research effort will be essential to get private industry closer to scalability. In 2019, the FDA and USDA agreed on the approval process for cultivated meat for human consumption, and the FDA recently approved a "slaughter-free" chicken product from Upside Foods.[38] To help reduce cost, the federal government's top priority should be to facilitate access and information sharing regarding the new wave of alternative proteins that are currently emerging. To capture the growing amount of information in this field and reduce redundancy, the government should create open-access repositories that may include the following: feedstock data for fermentation, animal protein characterization, animal cell line banks, and microbial libraries.[39] These

repositories will increase access to relevant data and materials, allowing companies to apply more resources toward other stages of production.

Biomining Through Biotech

The DoD requires metals and rare earth elements (REE) for various defense products, such as communications equipment, stealth platforms, and precision-guided weapons. Since the 1990s, mining critical minerals and REE has primarily been conducted overseas due to lower labor costs and environmental considerations.[40] Traditional mining requires large amounts of energy for smelting or noxious chemicals for hydrometallurgy to separate the metals from the ore material. In contrast, biomining uses microorganisms like bacteria and fungi to extract valuable metals from ores through bioleaching and bio-oxidation processes. Biomining can reduce the environmental impact of mineral and REE extraction and provide a means of "onshoring" mining operations when used on recycled electronic or industrial waste streams.

Projections show that the demand will double for critical minerals like lithium, graphite, nickel, cobalt, and REE in the next 15-20 years.[41] This increase results from a growing global population, a transition to renewable forms of energy, and greater demand for electric vehicles and other goods requiring these materials. Due to the depletion of productive mines, mining in the future will depend on lower-grade ores and alternative sources like deep mines and seabed. These may not be as easy to access. Still, they will be increasingly important.[42] Globally, biomining accounts for approximately 15 percent of copper and five percent of gold production.[43] Biomining can make minerals in lower-grade ores more accessible for capture and decrease the energy and caustic chemical requirements.

Biomining can help reduce dependence on overseas sources. China currently supplies over 70 percent of the global REE, down from 97 percent in 2009.[44] For particular REEs such as dysprosium and terbium, China's market share exceeds 98 percent.[45] Heavy government subsidies, lax environmental regulations, and poor labor laws dominate China's REE market.[46] Within North America, most REE deposits are in Canada and the western United States. The United States dominated the REE market until the mid-1980s when China began issuing export tax rebates to offer REE at lower prices.[47] By 2015, aside from some recycling, the United States was 100 percent reliant on import sources for 19 critical minerals.[48] Biomining has the potential to fill a vital role in diversifying critical mineral and REE supply chains, thereby reducing reliance on geopolitically unstable regions.

Biomining is a generic term that refers to using microorganisms to extract metals from ore through bioleaching or bio-oxidation.[49] Bioleaching is a form of biohydrometallurgy that uses different microorganisms to solubilize metals from sulfide ores using microbial metabolic processes. Bioleaching can only work in newly mined ores or materials leftover or impractical to mine using conventional mining methods, such as mine tailings.[50]

Some emerging biomining techniques minimize or eliminate energy-intensive extraction, grading, and grinding requirements. One of these technologies is a proposed bioleaching process involving deep in situ bioleaching of a sulfidic ore body.[51] In this case, a deep ore block would be hydro-fractured to open flow channels and then injected with acidic iron-rich leach liquors. These liquids would then be captured to strip the copper from the fluid and regenerate in surface bioreactors for reinjection. This process would remove the energy requirements to mine and crush the ore body, significantly reducing the environmental impact.

The genetic modification of microorganisms for biomining is typically deemed unacceptable due to the potential release of these organisms into the environment with unknown consequences, making it difficult to obtain regulatory approval. However, there are researchers at Cornell working on the directed evolution of certain microbial strains within labs that may help produce a microbe that can bioleach REE more efficiently than existing strains.[52] Ultimately, genetically modified bacteria could be used in a controlled industrial environment to leach REE from waste materials and increase yields in bioleaching and bio-oxidation of sulfide materials.[53]

Biomining provides a means of "onshoring" some mining operations and decreasing the environmental impact of mineral and rare earth extraction. The demand for critical minerals such as lithium, graphite, nickel, cobalt, and REE may increase significantly within the next two decades. Biomining of existing mine tailings and electronics waste can diversify critical mineral supply chains and reduce reliance on geopolitically unstable regions. However, biomining is still an emerging technology. It faces many challenges, including high start-up costs, lack of clear regulatory guidelines, the increased time required for extraction compared to traditional chemical methods, and limitations of microbes. Continued research and development may address some of these challenges and improve the efficiency and applicability of biomining in the future. There are a few ways in which the United States can help this industry.

As a part of investment in the overall bioeconomy, the United States should promote research and development in biomining. One way to promote research is by providing funding grants for basic research. The DoD should particularly prioritize research that would offer alternative supply chains for REEs. One such program is the Environmental Microbes as a Bioengineering Resource program that the Defense Advanced Research Projects Agency

(DARPA) currently sponsors. Companies that can effectively recover critical materials from existing mine tailings can be eligible for federal tax incentives. Establishing a revolving fund program, similar to what the Clean Water State Revolving Fund program provides for municipal wastewater treatment plants, would be a beneficial measure to encourage the retrieval of REE and crucial minerals from electronic or other waste materials. This program should offer low-cost financing for equipment such as bioreactors. Relatedly, the United States should consider establishing lifecycle accountability regulations for e-waste to ensure these materials are reused and recycled.

Improving the Environment through Biotech

Climate change, food insecurity, and access to vital resources are some of the most significant challenges facing the United States and its allies. Biotechnology is uncovering solutions to these pressing issues, but policymakers must do everything possible to foster the industry's innovation, effectiveness, and sustainability. Innovations and applications of biotechnological approaches to developing biofuels, biomanufactured products, carbon capture, crop resilience, and biomining offer tantalizing solutions to the threats presented by climate change and the demands of humanity's future development.

Human Applications in Biotechnology

In addition to its far-reaching impact on climate and agriculture, biotechnology has revolutionized numerous aspects of human health. The techniques and approaches employed to enhance yield efficiency, develop plants that can withstand drought, and mitigate the effects of climate change have the potential to address pressing human health issues. Remarkable

advancements in this field have brought about transformative applications and novel avenues to combat diseases, enhance human performance, and revolutionize healthcare. The synergy between biotechnology's environmental and human applications highlights this field's radical potential in shaping a sustainable and healthier future.

Over the last two decades, significant achievements such as mapping the human genome, Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology for DNA editing, biometrics, and material science have contributed to the health and pharmaceutical sector of the United States. Governments and private companies must leverage biotechnology in the coming decades to enhance and improve health outcomes for their citizens. These developments have the potential to bring about economic and social prosperity. However, if the international community fails to reach a consensus and adopt moral guidelines, the race to advance human health has the potential to threaten the global community. This section will explore three areas of human health application of biotechnology and conclude with recommendations that will ensure safety and security.

Wearable Technology

Wearable devices are among the first technologies to proliferate in the human health sector. The desire for portable technology dates to the first wearable abacus ring from the Qing Dynasty. According to one report, over two-thirds of Generation Z and Millennial consumers use wearable healthcare technology.[54] The FDA defines a medical device as "any instrument, machine, contrivance, implant, in vitro reagent intended to treat, cure, prevent, mitigate, diagnose disease in man."[55] The regulation of wearable devices depends on their intended use and the risk to the wearers. These types of devices can greatly enhance the quality of life for

numerous users by enabling them to better their dietary habits, track their sleep patterns, and optimize their athletic abilities. These devices can be wearable or implantable. It is expected that private industries will be the driving force behind the future development and use of human-machine wearables, with the goal of generating profit. However, the public sector will also reap benefits from these advancements. In terms of national security, there are advances in research to understand the use of wearables to increase military readiness and enhance human senses and capabilities.

The DoD is researching wearables to find solutions that allow the military to detect illness before outward symptoms. This research is significant to maintain military readiness in an event such as a global pandemic where it is vital to isolate infected individuals to prevent disease spread. Investments across organizations such as DARPA, the Defense Innovation Unit (DIU), and the National Institution of Health are funding efforts to advance wearable medical sensors across these intended uses.[56] The U.S. Space Force is also executing a pilot program where Guardians can use "Oura Rings" and "Garmin" watches as wearable devices to promote general wellness over physical strength and endurance.[57]

The demand to enhance various industries such as healthcare, fitness, logistics and transportation, construction, retail, entertainment, and education is being driven by smartwatches and other wearable technologies. However, there are some companies and countries that are exploring the use of wearables to boost human performance. In the United States, medical wearable devices and implantable devices fall under FDA jurisdiction, which only looks at the safety of wearable devices. However, there are concerns regarding the lack of ethical implications when evaluating devices that surpass current human limitations. DARPA is already engaged in research projects examining technologies that can enhance Warfighter capabilities.

These include ocular enhancements that enable the user to see beyond the human visual spectrum, enhanced auditory abilities, and direct neural enhancements to allow two-way data communications.[58] The FDA must provide more guidance to balance the ethical implications of these wearables used for human enhancements while allowing the DoD to maintain a competitive advantage against its adversaries.

The sector of wearable technology encounters various obstacles concerning safety, security, and ethical use. The convergence of medical and digital information technologies poses unique challenges requiring industry and government engagement to consider regulatory jurisdiction, digital privacy, and data security. Ensuring the protection of information is of utmost importance. In 2018, service members on a military base in Afghanistan used a common fitness tracking application called Strava which revealed a detailed map of the location and staffing of military bases. More recently, there have been more obscure uses of fitness apps, such as an anonymous user who set up fake running segments across secret military facilities in Israel, which enabled the user to bypass Strava's privacy settings, illuminating maps of secure facilities.[59]

Recommendations for Wearable Technologies

For the United States to lead the establishment of international norms regarding wearable technologies, policymakers should write good rules to be in a defensible position to lead an international effort. The United States should also participate in international advisory councils focused on global health protection to direct research and development toward safe and ethical technologies. These councils can also establish a framework that adheres to high standards of security, privacy, and ethical conduct. As technology develops, policymakers can prioritize

information and data management security across a system's lifecycle to prevent data exploitation. Finally, ensuring that the technology adheres to international safety standards and is interoperable is important to hold manufacturers accountable for authorized use and safety compliance.

Hereditary Human Genome Editing

A fast-growing field in human biology called hereditary human genome editing (HHGE) holds great potential. Enabled by the Human Genome Project and CRISPR-Cas9 technology, human genome editing is a reality with a vast promise to cure or prevent disease or disability. Advocates are excited about the potential to one day eliminates devastating heritable single-gene disorders such as Huntington's disease. Recognizing the value of this technology, The White House set a goal to advance techniques in gene editing in its recently released *Bold Goals for U.S. Biotechnology and Biomanufacturing*.[60] But the United States and the global community should proceed cautiously. This technology also opens the possibility to improve strength or intelligence; select genes for preferred traits such as eye color; or introduce genetic enhancements that do not naturally occur in humans, such as resistance to disease or radiation. There has been an effort to establish an international governing framework for human genome editing research in recent years. The aim is to maintain a balance between the potential uses and the risk of misuse.

Guidelines for HHGE quickly developed when, in 2018, Chinese researcher He Jiankui stunned the world when he announced that he had genetically engineered human embryos resulting in live births. The scientific community quickly condemned his activities as premature, unethical, and morally indefensible. The Chinese government later found him guilty of illegal

medical activities resulting in a fine and a three-year prison term.[61] But it is unclear if He Jiankui received approval or funding from the government for his research. Other CRISPR research and publications on biotechnology and biowarfare suggest an interest in China in exploiting this technology. For example, in October 2022, researchers from the Chinese Academy of Military Sciences reported successfully inserting DNA from a tardigrade, a microscopic organism known as a water bear, into human embryonic stem cells. The inserted gene enables the tardigrade to produce radiation-resistant proteins. As a result, 90% of the human embryonic cells that were edited genetically became resistant to radiation. Researchers view this experiment as a precursor to "super-tough soldiers who could survive nuclear fallout."[62]

The United States and the international community will need to consider the repercussions of government-regulated experiments that value the good of the state over the autonomy of individuals and how the introduction of desirable traits could enhance a population over time. He Jiankui's research led to a flurry of activity from international organizations to update position statements, recommendations, and proposed regulatory frameworks. A 2020 review of the global policy landscape on HHGE found that 96 of 106 counties examined had relevant policy documents. Of those 96, 75 countries have laws or policies that prohibit HHGE.[63] Divergent policies in this area could contribute to an increased risk when it comes to the development of HHGE technologies.

The United States and China take different approaches to regulating HHGE. On the federal level, since 2016, the United States has effectively prohibited HHGE through the annual appropriations bill by prohibiting the review or approval of HHGE clinical trials. The appropriations bill also blocks federal funding for human embryo research or tracking of non-federally funded human embryo research.[64] On the state level, laws vary from not having

legislation for human embryo research to complete restriction to permitting research with varying limits on how long research can continue post-fertilization.[65] The most restrictive laws define a fetus from the time of conception, a notable deviation from the scientific definition, which defines the transition from embryo to fetus at the beginning of the third-month post-fertilization.[66]

Since He Jiankui's research, China has strengthened its position on HHGE. The China Biosecurity Law implemented in 2020 includes the Chinese Civil Code, which states that "medical and scientific research activities concerning human genes and embryos, among others, shall be performed according to laws and administrative regulations and relevant provisions outlined by the state without endangering human health, violating moral principles, or damaging public interest." Additionally, the Criminal Law Amendment XI prohibits human cloning and human germline genome editing for clinical purposes.[67] China also updated its *Measures for the Ethical Review of Life Science* and *Medical Research Involving Humans and issued Guidelines to Strengthen the Governance over Ethics in Science and Technology*. [68] They increase the scope of activities subject to ethics review, lists violations subject to sanctions, and clarify the informed consent process.[69] Regrettably, the new laws in place lack clarity when it comes to privately funded research and provide exemptions for hospitals, universities, and research institutions that have their own codes of conduct.[70] Moreover, the laws and guidelines related to this issue are scattered across multiple documents, each with varying levels of authority or enforcement. This fragmented landscape may pose challenges for researchers in China, making it difficult for them to navigate the regulatory framework effectively.

There has been significant movement in the international scientific community to establish a common framework for continued research in this area. Under the leadership of the

U.S. National Academy of Sciences and The Royal Society, the International Genome Editing Commission set forth a responsible way ahead that neither stifles scientific advancement nor allows for HHGE research to accelerate unchecked. Similarly, the World Health Organization has offered a framework for the regulatory governance of HHGE.[71] The strength of these recommendations depends on the level of implementation and enforcement by individual countries. In the absence of established regulations and customary practices, researchers may opt to carry out their work in countries with fewer limitations, particularly if they perceive an opportunity to gain from the technology.

Recommendations for HHGE Research

For the United States to assert its leadership in establishing international norms in HHGE, policymakers must prioritize the following critical recommendations. First, the appropriations bill should change to explicitly allow federal funding of embryoid research in alignment with the International Society for Stem Cell Research. The bill should also allow the NIH to be a repository for non-federally funded human embryo research to increase transparency. The FDA must also track any submissions for investigational new drugs or biological products that involve human germline genome editing. Last, the United States should adopt the Heritable Human Genome Editing recommendations to develop an oversight mechanism. This oversight could reside with the NIH after the appropriations bill is modified. The implementation of these recommendations by the United States would not only support the international commission but also establish a solid foundation to safely advance gene-editing techniques.

Longevity Technology

Human health guidelines should also encompass the ever-evolving realm of emerging technologies within the biotech industry. Aging as a field of scientific study has only emerged in recent decades and is gathering momentum quickly. Today hundreds of research centers, universities, and companies around the globe are pouring billions into this research. Three key findings opened the floodgates of scientific inquiry into aging: first, was discovering a close resemblance of mortality curves among disparate organisms indicating some commonality in the aging process; second, evidence that the rate of aging could be regulated; and third, the longevity-inducing effects of caloric restriction across a broad array of species.[72] The classification of the nine hallmarks of aging and the introduction of the information theory of aging has offered a broad array of possible avenues to intervene in the aging process to slow or even reverse it. The progress made in our understanding of aging is heralding a transformative "longevity paradigm shift," giving rise to a burgeoning ecosystem focused on anti-aging. Healthcare, health technology, life sciences, and lifestyle companies are all actively competing for a share of what promises to be a rapidly expanding market. Empowering the treatment of root causes of aging and disease aims to extend human lifespans and significantly enhance health spans to unprecedented lengths. Some prominent longevity researchers believe that the first human to live to 150 is already alive today.[73]

The coming longevity paradigm shift will have critical geopolitical consequences relevant to national security. If the United States is to remain competitive, it must stay at the forefront of longevity research because China has made significant investments in gerontology and life extension research since the 1980s. A significant amount of research has been motivated by the necessity to address the consequences of a declining population and workforce.[74] China

has funded numerous research centers, laboratories, and institutions nationwide for basic and translational research into aging.[75] Investment in these new frontiers could destabilize international relations in ways that are not yet fully understood. Enhanced longevity and its implications should make their way onto the agenda across the global regulatory authorities to ensure adequate consideration of international norms and standards that address the coming changes.

Recommendations to Prepare for Advancements in Longevity

The field of longevity science presents a unique chance for the United States to enhance social well-being and tackle concerns regarding national security. Policymakers should consider social, political, and economic consequences as the United States prepares for a future with longer human life spans. A scenario where the ultra-wealthy live healthy 150-year lives while the rest of the population lives half as long would lead to unprecedented inequality. To mitigate this, U.S. policymakers could classify aging as a disease to broaden accessibility across the healthcare system. Health insurance companies could then channel research funding into anti-aging therapies with the potential to reduce end-of-life treatment costs.[76] Other social and political systems will need to be reviewed and modernized. For example, implementing term limits in politics will be imperative to prevent politicians from exerting their influence for prolonged periods. The implementation of suitable measures can ensure that the United States aligns its public policies with technologies that can compete effectively in the global community.

Ethical Considerations for Human Applications

The examples above illustrate the rapid progress of biotechnology and its potential to benefit humanity. However, without international frameworks and standards to regulate the development of these human applications, there is a risk of potential misuse and inequity throughout the global community. Many countries have already moved beyond whether researchers should pursue these fields and are increasingly becoming acceptable norms. The application of biotechnology to human health endeavors has sparked ethical debates, leading to both positive and negative reactions from the public. Most people are optimistic about this technology, given its ability to improve quality of life.[77] However, there is less optimism and vastly different opinions globally when used for enhancements, modifications, personal conveniences, or choices. For instance, the United States is monitoring Dual Use Research Concern (DURC) because it opens the door to genetic engineering for military and private research.[78] Entities may sell pathogens, use biological weapons, and misuse chemicals due to poor safety awareness while remaining secret about their use and research. There is a concern that certain countries may utilize genetic engineering to enhance their military personnel and gain an unjust edge over their adversaries. Furthermore, there is the possibility of editing genes to target a particular ethnicity or lineage for the benefit of future generations. If debates are avoided in this field, it could lead to a lack of transparency and make the United States vulnerable to attacks. It will also hinder the opportunities to incorporate offensive biotechnology in biowarfare and biosecurity in international discussions or as a tool for deterrence.

Recommendations to Maintain Ethical Guidelines

In an era of great power competition, nations must agree on the rules for using this technology. The United States must spearhead the development of an international ethical agenda mandating oversight of biotechnology for human applications. The United States must also work with global regulatory authorities to adopt critical norms and standards to harmonize public and private investments, priorities, and policies across the human-related biotechnology spectrum. The United States must stay competitive in these advancements to deliver capabilities to its citizens and the warfighter. Innovation must also include guidelines that will allow the United States to break new ground, considering both the risks and opportunities of biotechnology.

To promote an international ethical agenda that emphasizes oversight of human applications in biotechnology, the United States should advocate for the adoption of various governance standards by all governments. First, it is important for the international community to establish points of agreement or convergence, develop effective decision-making processes, and foster collaboration whenever required. Certain procedures may involve establishing criteria for creating registries and submitting reports and protocols for conducting clinical trials. These measures can also be utilized to establish procedures for reporting illegal, unregistered, unethical, or unsafe research practices. This will safeguard populations and communities from potential harm. Last, it will be important for government leaders interested in adopting emerging technologies to leverage existing frameworks and institutions to effectively educate and engage people within their borders.

Creating a Safe and Ethical Environment to Advance Human Health

If the United States fails to promptly advance its agenda, China may take the lead in the field of biotechnology for human health applications. China is actively striving to surpass the United States and has already achieved significant milestones, such as being the first country to successfully bring genetically engineered humans to full term. To prevent illicit and unethical practices and foster a secure and productive environment to explore the realms of possibility, it is imperative for the United States to take the lead in international initiatives aimed at establishing ethical norms in biotechnology.

Security and Resilience in Biotechnology

Security and resilience in biotechnology are intrinsically linked to the advancements and applications of biotechnology in human health. Investing in robust security measures safeguards the integrity and efficacy of human health applications of biotechnology. Additionally, building resilience in the industry enhances our capacity to respond swiftly and effectively to health crises, strengthening overall human health applications. The close relationship between security, resilience, and human health applications of biotechnology highlights the vital role of biotechnological advancements in protecting and promoting the well-being of individuals and communities.

Human capital, pharmaceutical supply chain resilience, biological defense capabilities, and communication concerning biotechnology are all critical factors that impact security. Human capital development is essential for the biotechnology industry to thrive. By investing in human

capital development in the biotech industry, the United States can resource development of new vaccines, drugs, and biodefense strategies. The pharmaceutical supply chain is crucial in providing critical medicines and vaccines to protect the population from debilitating conditions. However, disruptions to the supply chain can have serious consequences. Likewise, biological defense capabilities protect the population and maintain societal stability by detecting and responding to biological threats. Last, all these factors rely on effective communication to help the public comprehend the potential risks and advantages associated with the industry.

Human Capital Challenges in Biotechnology

An emerging issue in the biotechnology industry is that the number of individuals in the United States who are prepared, inclined, and available to supply the industrial base needs to be revised. The shortage of skilled professionals in the biotech industry lessens the domestic capability to produce, innovate, and endure any significant protracted public health crisis or national security event. The United States, once regarded as the undeniable global leader in the biotechnology industry, has ceded significant ground to global competitors in terms of innovation and production.[79] In today's global economy, nearly every Organization for Economic Cooperation and Development (OECD) country has access to the technology, equipment, and capital needed to produce standardized and successful products.[80] The United States biotechnology industrial sector must address a potential shortage of skilled manpower or risk losing its competitive edge.

The biotechnology industry's shortage of skilled workers can be attributed to the decreasing interest of people in the United States in science, technology, engineering, and mathematics (STEM) training over the past few decades. As the shift took place, there was a

notable industry focus on efficiency and cost reduction. Consequently, companies started perceiving labor as overhead rather than a valuable asset and began outsourcing it overseas, along with corporate knowledge.[81] The second challenge encompasses various barriers to attaining advanced STEM education. Biomanufacturing, research, and development processes are increasingly technical and sophisticated, requiring robust training and hands-on experience. The groundwork for this education begins in primary school, yet there are areas that require improvement in U.S. K-12 STEM education.

Significant strides have been made in recent years to narrow the biotechnology human capital gap, yet the challenge still demands further examination and attention. One area in which industry, academia, and policymakers should prioritize is incentivizing and raising awareness of biotechnology as a viable career path for those already interested in science. There is a significant number of medical track attrits who are ideal candidates to help fill the labor pool gap at different levels. Academia should take steps to fast-track their career paths into biotechnology fields. Specifically, a combination of career-based government grants, loan forgiveness, and industry scholarships can incentivize the attrits - who have already invested time, money, and energy on foundational knowledge - to redirect their efforts toward biotechnology. Second, there remains a prominent flaw in the talent pipeline, particularly in the early stages, where the K-12 education system fails to equip students with the necessary STEM skills. The right balance between the physical and social sciences still needs to be discovered. However, the U.S. K-12 system must produce students with the foundational depth and breadth needed to solve problems across many fields, especially biotechnology.

A comprehensive strategy in human capital should also include reforms to immigration policy. Policymakers should consider improvements to the Visa Security Program (VSP) to

strengthen ongoing efforts aimed at mitigating the vulnerabilities of capital export in academia. To ensure a smooth visa application process, it is essential to maintain detailed records, provide adequate support for each recommendation, and have a robust feedback system with the Student and Exchange Visitor Program (SVEP). This ensures that initial support for recommendations stays in line with current activities. Before granting the award, it is important to consider what will happen after the visa expires. To reduce talent exportation, the United States should award student visas with clear pathways to retain those individuals in the United States upon completing their studies.

Strengthening the Biotechnology Supply Chain

Many individuals consume pharmaceutical drugs regularly to maintain their well-being. However, they may overlook the origin of these medications. When people cannot rely on regular access to essential pharmaceutical drugs, their quality of life is at risk, and their chances of survival are threatened. The societal cost imposed by a potential absence of these drugs presents national security challenges. The United States would need to allocate additional resources toward the well-being of its citizens, which could potentially impact funding for other initiatives. Additionally, military readiness depends on access to essential pharmaceutical drugs to fight and support military forces in conflict. The United States is determined to avoid dependence on an adversary for vital life-saving medicine in case of a future war or national emergency.

The pharmaceutical industry worldwide is at risk of experiencing disruptions in its supply chain, as well as facing threats from foreign adversaries. A March 2023 report highlighted

limited redundancy of facilities that manufacture Advanced Pharmaceutical Ingredients (APIs). Specifically, about one-third of APIs were manufactured by a single facility and another third by only two or three facilities.[82] Furthermore, approximately 80% of the world's APIs come from China, India, and other countries. The United States felt the effects of external dependence on these limited sources when India, the leading global supplier of 62% of APIs, imposed an export ban on medicines during the pandemic.[83]

The threats to the supply chain are wide-ranging, including a limited number of manufacturers, no visibility across the system, and variable threats such as weather, labor shortages, or pandemics. The United States produces only 12% of the world's API supply. The United States should increase domestic production and redundancy with allies to reduce volatility.[84] To be fully prepared for any potential disaster, the United States must have a strong network of pharmaceutical producers and suppliers and a reliable distribution system. This will significantly reduce the impact of any unforeseen events, whether caused by nature or human intervention.

Recommendations to Improve the Supply Chain

To improve the U.S. pharmaceutical industry, there are three specific areas that both policymakers and industry leaders should prioritize. The first of which is onshore production and capacity. The U.S. government must incentivize the industry to revamp domestic production of APIs. The United States can accomplish this through grants, access to capital, and tax incentives. As onshore efforts increase, policymakers must collaborate with states to ensure that new facilities have an adequate workforce to operate them.

Bringing a new supplier into the market can also be time-consuming. The process of introducing a new API supplier typically spans 12-15 months, accounting for regulatory approval time. This endeavor is also financially demanding, leading most price-sensitive generic medicines to rely on only one or two qualified API sources. Developing a new API can exceed four years, imposing a significant burden on API manufacturers, especially when numerous foreign API sources are readily accessible. Policymakers should advocate for government oversight agencies such as the FDA to streamline processes and minimize regulatory hurdles.

The second focus area is the U.S. National Strategic Stockpile. Congress must mandate that the Department of Health and Human Services (HHS) carries out a comprehensive review of the stockpile to ensure that it possesses sufficient resources to meet the government's potential demands during times of necessity. The stockpile should include APIs and manufactured pharmaceuticals that rely on one global supplier to produce them. To mitigate any potential risk to national security resulting from disruptions in the supply chain beyond the control of the United States, it is essential for maintainers to rotate a six-month supply of critical life-saving drugs and replenish supplies as needed. To increase efficiency across agencies, HHS should collaborate with DoD and other federal agencies to prevent duplication of effort in creating similar stockpiles.

Lastly, the United States should establish dependable trading partners for the supply of APIs. Congress should also direct agencies to collaborate with European allies to secure alternative sources of supply in case of a national emergency or to address shortages resulting from disruptions in the supply chain. Notably, Italy’s rise as a prominent pharmaceutical producer has been attributed primarily to private investments in small and medium-sized

companies.[85] Working with top European producers like Italy will provide greater resiliency for the United States.

How the United States Can Build a Better Biological Defense

The increased prevalence of naturally occurring biological threats and the ability of countries to intentionally use biological weapons to threaten U.S. national security. In today's world, the rise of global travel, urbanization, and habitat encroachment has led to a higher risk from naturally occurring biological pathogens.[86] These factors often drive increased contact between humans and wild animals, resulting in increased zoonotic transmission of biological pathogens to humans and the global transmission of biological pathogens between humans. The statistical increase in the global transmission of zoonotic diseases and biological pathogens over the past forty years shows the increasing prevalence and threat of naturally occurring biological pathogens with diseases such as the Ebola Virus, H1N1 Virus, and Avian Influenza.[87]

The United States must improve its capability to detect biological threats at the state and federal levels. However, there are capability gaps within state public health laboratories and insufficient federal surveillance systems. It is evident from the COVID-19 pandemic that biological threats can have a significant impact on the U.S. national security objectives, including economic prosperity and domestic security. It shows the inadequacy of the U.S. domestic public health system to detect, identify, and respond to unknown biological threats.

At the state and local levels, public health departments and labs serve as part of the first line of defense by detecting biological threats to the homeland. Laboratories' quality and diagnostic testing capability vary from state to state, causing a gap in the domestic public health surveillance and detection network.[92] At the federal level, federal public health labs and the “BioWatch” program exist. BioWatch is a biological surveillance system designed to detect specific biological agents in aerosol form. It spans across 30 urban locations.[93] "Generation 2" of BioWatch is currently used, with "Generation 3" on hold due to technology gaps. Recent GAO reports highlight the limited ability of BioWatch to detect known biological agents in aerosol form. Due to the latest advancements in biogenetics by potential adversaries, BioWatch needs to have the ability to detect unidentified biological agents, not only in aerosol form but in both soil and water as well.

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Recommendations to Improve Biosecurity

Biotechnology can strengthen local and state public health laboratories and enhance the BioWatch program. Further expansion of bioindicators with genetically modified organisms could enable BioWatch to detect known and unknown biological pathogens in soil, water, and air. Policymakers should provide local and state public health laboratories with next-generation sequencing technology, the rapid sequencing of biological pathogens can be achieved as an initial defense measure.

One way to maximize the benefits of biotechnology for improving public health is by shifting state and federal investments toward this field. Both state and federal investment in long-term applied research will enhance biosecurity programs. The federal government projects to spend over $80 million on Generation 2 of BioWatch. The federal government also plans to spend $200 million over the next ten years for future versions.[94] The government should discontinue funding for Generation 2 of BioWatch, reprioritizing $140 million to fund local and state public health labs with next-generation sequencing technology and reprioritize $140 million towards applied research on developing genetically modified bioindicators that can detect known and unknown biological toxins in sea, air, and land. Furthermore, Congress should strengthen knowledge management of biological pathogen genomics by enacting legislation requiring all local, state, federal, and public biological labs to cross-check all suspected biological pathogens with the National Center for Biotechnology Information (NCBI) database. If a lab comes across a new pathogen, it can submit the genotype to NCBI.

Communicating Biotechnology to Mitigate Risk

As scientific advancements continue to accelerate and grow increasingly complex, there is a challenge in explaining the benefits of science and innovative economies to societies. The field of biotechnology has made significant advancements in recent years, but its impact may not always be immediately clear to people. This lack of understanding has led to feelings of exclusion, distrust, fear, and hesitation toward embracing the benefits of innovative biotech products. The outcome can change consumption habits, health behaviors, national economies, and competitive advantage. The desire for knowledge in humans stems from a need to reduce fear of the unknown, maintain a sense of control, and prevent exclusion. Information deprivation can evoke anxiety, mistrust, and a desire to fill the gaps with anything available.

Examples include the science of genetically modified crops, which has been plagued by misinformation for over two decades, and the temporary suspension of the AstraZeneca COVID-19 vaccine in numerous countries due to misleading and incomplete information flows, highlighting the significant risks posed by the spread of misinformation and targeted disinformation against the biotechnology industry. The World Health Organization even declared a state of infodemic during the COVID-19 pandemic due to the rapidly increasing amount of information, including mis- and disinformation, on the causes and treatment of the disease.[95] The combination of information power and resistance to progress could potentially disrupt the industry's cost-benefit analysis and impede necessary development to tackle climate change, food security, and healthcare challenges. All this poses risks in maintaining a competitive edge and threatens national security.

Given the projected economic impact of the biotechnology industry, estimated to reach up to $4 trillion over the next 10 to 20 years, it is imperative to develop technological methods

and policies that effectively address the threat of misinformation and disinformation, particularly concerning science and technology.[96] An analysis conducted by McKinsey Global Institute reveals that over 50 percent of the potential impact of biotechnology in the next decade may hinge on the acceptance of consumers, society, and regulators. This percentage could increase to 70 percent within the next two decades.[97]

Given the capabilities of social media platforms and technology for spreading misinformation and deliberate disinformation, it is unlikely that their dissemination will decline. To combat the dangers of false information, it is essential to implement immediate technological actions and long-term strategies to strengthen a person's ability to resist false information and encourage informed decision-making when receiving information. Promoting media and science literacy, as well as enhancing science communication, will play a role in this effort. The level of information literacy in a nation is crucial for its security and reflects its vulnerability to information attacks and manipulation.

Recommendations to Improve the Information Environment

To enhance the information environment surrounding the biotechnology industry, there are four policy matters to be considered. First, AI-based tools such as bot detection, fact-checking, debunking, source credibility scoring, and educational resources should be available to prevent false information from spreading on social media platforms, search engines, and other internet content. These tools can utilize deep learning and machine learning to classify and perform tasks using examples from images, text, or sound, thereby reducing human factors essential considering today's information volume. To combat the spread of misinformation, an

automatic corrective information layer should be in place after debunking. This will help prevent false information from becoming more entrenched.

Second, policymakers and industry should explore the involvement of the gaming industry to create games that address the spread of mis- and disinformation while educating younger generations and gaming communities on how to navigate the information environment. Opportunities are starting to abound in some communities.

Third, prioritizing the information gaps where perceived fears are prominent enables practitioners to enhance the effectiveness of scientific communication. By focusing on these areas, practitioners can effectively address the additional information needs of the audience. Policymakers should monitor how communication flows in communities that are often overlooked and work with community leaders to build more effective channels.

Lastly, policymakers should reinforce science and media literacy education in the K-12 system to strengthen critical thinking and source navigation knowledge for better media and information literacy, including social media. Investing in this area can have a positive impact on developing a skilled workforce as students become more engaged in the physical sciences.

Working Towards Enhancing All Dimensions of Society

Human capital, pharmaceutical supply chain resilience, biological defense capabilities, and communication concerning the biotechnology industry all play essential roles in national security. These factors are interconnected and contribute to developing a comprehensive strategy to counter biological threats. By investing in these areas, the United States can better protect the domestic population and maintain societal stability in the face of biological threats.

Summary

Biotechnology is revolutionizing the energy, manufacturing, agriculture, mining, and human health sectors. Continued leadership in biotechnology is critical for the United States. The Eisenhower School for National Security and Resource Strategy conducted a comprehensive review of many aspects of the biotechnology industry and thoroughly assessed potential risks in light of the recent Executive Order on *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure Bioeconomy*. The seminar successfully developed robust recommendations based on their research to effectively achieve national security objectives in the field of biotechnology.

China has a comprehensive policy framework to take the lead in the field of biology in the 21st century. Its 13th Five-Year Plan, spanning from 2016 to 2020, is a key starting point for this endeavor. China is pushing forward its industry at a rapid pace and is poised to surpass the United States in the coming decades.[98] The U.S. government is working on a plan to maintain its dominance in the sector, acknowledging the importance and high stakes involved. However, there is a pressing need to go above and beyond to outperform competitors. To address the most critical vulnerabilities in the industry, the United States should prioritize early investment in research and development aimed at mitigating environmental risks, establishing global standards for human health, and encouraging more people to pursue careers in biotechnology to bolster the workforce.

The first key area, reducing environmental threats, is where biotechnology has the potential to significantly improve manufacturing, food production, energy, and mining applications. Lawmakers must prioritize policies that promote innovation, sustainability, and effectiveness in this field. These policies can improve investment in emerging technologies,

including biofuels, biomanufacturing, carbon capture, crop resilience, and biomining. Unfortunately, public funding for research is currently at a historic low. To promote growth and development in the industry, federal and state governments should expand federal subsidies, grants, loans, and tax incentives. To further drive growth, lawmakers should consider transparent and efficient regulatory frameworks to expedite the delivery of these products to market and create the infrastructure to support these applications to encourage widespread use throughout the commercial sector.

Next, policymakers should place a high priority on the establishment of global standards and guidelines concerning the application of biotechnology in human health. This will ensure the adoption of ethical and secure practices in rapidly expanding fields. In particular, the United States should safeguard advancements in hereditary human genome editing (HHGE) to actively promote the progress of this fast-growing field by permitting federal funding for embryonic research and tracking non-federally funded research. This advancement can be done safely if the United States follows the guidelines put forth by the International Commission on the Clinical Use of Human Germline Genome Editing as an oversight mechanism.[99] Given China's rapid advancements in this field, aligning U.S. laws with international guidelines will ensure that researchers can safely make progress in this domain.

As biotechnology advances in providing solutions for human health and the environment, the United States must ensure a plentiful supply of skilled professionals to propel these sectors forward in the coming decades. Policymakers must drive K-12 education that lays a strong foundation and offers a wide range of opportunities for students interested in pursuing science, both academically and professionally. Policymakers should also collaborate with the private sector to expand opportunities for individuals with associate degrees, increasing the pool of

qualified candidates for entry-level positions. Additionally, the United States should enhance its visa programs to attract and retain talented immigrants, reducing the outflow of skilled individuals to other countries.

As the United States explores new possibilities in biotechnology, it is important to address the major vulnerabilities in the supply chain and the potential for mis- and disinformation spread across society. The challenges to the supply chain are diverse and include factors such as a limited number of manufacturers, lack of system visibility, labor shortages, and other external factors. To address these concerns, the United States should collaborate with dependable trading partners and domestic suppliers to secure alternative sources of supply and maintain strategic stockpiles as needed. Policymakers should also guarantee the accuracy and dependability of information shared to promote the adoption of modern technologies. Leaders at various levels of government must prioritize effective methods for detecting misinformation and ensure that educational materials are readily accessible to all. Communication will continue to be a challenge since social media platforms are not liable for third-party content generated by users. A potential update to the Communications Decency Act could be to hold platforms liable if they are unreasonably creating an unsafe environment.[100]

The biotech sector is chock full of threats and opportunities. Whether the United States maintains its lead in biotech will be a huge factor in determining whether the United States is able to maintain its position atop the international order. The recommendations set out here will help the United States maximize the incredible potential of biotech for good and avoid the pitfalls of the transition from the century of physics to the century of biology.

Appendix: The Role of Biotechnology in the China-Taiwan Conflict

According to the U.S. Department of Defense's (DoD's) review of military and security developments of the People's Republic of China (PRC), the PRC's 20th National Congress prioritized modernization of its forces by 2027 to be a credible military force as it pursues Taiwan reunification.[1] While the PRC desires peaceful reunification with Taiwan, it has left open the possibility of force.[2] The DoD assessed that the PRC's options might involve biological weapons and toxins, which can be used for both military and civilian purposes.[3] This analysis examines China's potential for the use of biotechnology in a conflict. It proposes that Taiwan, in collaboration with its allies and partners, can leverage biotechnology to proactively prepare for and deter potential attacks.

If a conflict occurs between China and Taiwan, it could lead to a significant loss of life, put allied troops at risk of infectious diseases and biological weapons, and disrupt global pharmaceutical supply chains. Given that 2027 is a major military milestone for the PRC, the United States has limited time to help strengthen Taiwan's capacity to improve medical research and therapeutics for existing infectious disease threats, improve pharmaceutical supply chains, treat war-wounded and mass casualties, and conduct bio-surveillance and biodefense.

To prepare for conflict, the U.S. military should evaluate other partners through existing security cooperation relationships utilizing the U.S. Embassy teams, military security cooperation officers, and the guidance set forth by the DoD's biomanufacturing initiative.[4] The U.S. government should create a multilateral task force under Indo-Pacific Command that assesses a partner's ability to deploy countermeasures, casualty treatment, and preparedness in the event of biological warfare or conflict with the PRC over Taiwan. The task force's capability assessment should encompass virtual surveillance and data processing of biological information

obtained from remote sensors deployed in the field. It should also incorporate relevant inputs, such as information provided by the combatant command regarding ground conditions to effectively monitor the occurrence and spread of diseases and health risks in the event of a potential conflict. There should also be an expansion in the State Department's science and technology counselor workforce in the region. This expansion would facilitate their involvement in reviewing relevant agreements and engaging in multilateral discussions pertaining to biotechnology export controls.

Key areas of concern for the United States in a potential conflict include arboviruses, diarrheal diseases, emerging infectious diseases, multidrug-resistant organisms, respiratory viruses, and vectors and vector-borne illnesses.[5] Collaborations with researchers across the Indo-Pacific region are aiding in the comprehension and management of infectious diseases. The United States should engage in greater sharing of information and sample collection of these diseases and illnesses. This can be achieved by leveraging the vessels and locations of the U.S. Indo-Pacific Command across its area of operations, with Tripler Medical Center serving as a remote hub for analyzing genetic information.[6]

A China-Taiwan conflict could also disrupt supply chains for drugs and therapeutics. China’s growing focus on biotechnology within its manufacturing sector has the potential to enhance its capacity to exploit pharmaceuticals for advancing policy objectives. This could potentially allow them to disrupt the supply of critical therapeutics, including cardiovascular and cancer treatments, to Taiwan, the United States, and their allies.[7] The United States should increase its capacity in the U.S. Department of Health and Human Services Strategic National Stockpile program of drugs largely dependent on production from China and increase the capacity of domestic and allies' supply chains to provide alternatives in the event of a Taiwan

conflict before 2027. Eventually, the United States, Taiwan, and its partners should permanently move away from Chinese supply chains and establish permanent sources with other countries. The United States should utilize trade agreements with other countries and economic statecraft to decrease dependence on China for critical minerals, pharmaceutical products, and other materials in the supply chain.

Taiwan must also prepare for scenarios where a significant number of individuals may be injured. They must have the ability to prioritize and provide medical care to patients in both standard and non-standard settings, particularly during times of conflict. The U.S. military should work with its allies and partners to supply medical provisions to Taiwan by partnering with logistics bases and supply centers in the region. The United States can expedite the development of frameworks, sale, transfer, lease, or loan of biotechnology capabilities, equipment, therapeutics, and training. The existing Foreign Assistance Act (FAA) allows the United States to transfer articles and services from any agency to support foreign governments and international organizations in an "unforeseen military emergency or for other legislatively authorized purposes."[8] To immediately prepare for conflict, Taiwan should increase its capacity to treat war-wounded by stocking freeze-dried plasma, enhance interoperability through medical exercises, and increase telemedicine and virtual reality advancements. Freeze-dried blood plasma will help soldiers recover from injury faster on the battlefield than traditional thawed frozen plasma.[9] The United States should also help Taiwan expand the use of telemedicine and virtual reality to train medical professionals and treat patients in battlefield situations.

Last, the DoD should also increase the prevalence of body-worn sensors that monitor and predict warfighter health, readiness, and performance.[10] According to experts, China currently has the world's most advanced system for collecting and analyzing biometric data through

surveillance, and the United States must be able to compete in these cutting-edge technologies.[11] The sensors the United States should deploy before 2030 include wearable sensors, smartwatches, smart bandages, and rings coupled with artificial intelligence and machine learning to predict potential infection, detect the early onset of physical stressors in real time, and limit disease spread.[12] Employing these measures utilizing new technology in the biotechnology industry will help the United States support Taiwan in a potential conflict.

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