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**Industry Study**

**Final Report**  
***Biotechnology***



**The Dwight D. Eisenhower School for National Security and Resource Strategy**

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The views expressed in this paper are those of the authors and do not reflect the official policy or position of the National Defense University, the Department of Defense or the U.S. Government.

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## BIOTECHNOLOGY 2018

**ABSTRACT:** Biotechnology is a \$106.9 billion U.S. economic sector including over 2,200 businesses and projected annual growth of 1.7% over the next five years. Technological advancements in biology will eclipse these statistics. The question is *when* and *if* the United States will retain its waning competitive advantage. Biotechnology inches closer to a tipping point where its impact will rival the development of the internet. Public and private sectors best adapted for this tipping point will most effectively harness the opportunities while taming the challenges. Agriculture, healthcare, industrial materials, energy, and advanced manufacturing sectors actively seek to harness the science of biology to revolutionize their products and services, delivering paradigm-shifting solutions to complex problems from precision medicine to sustainable energy. These groundbreaking initiatives represent both tools and potential threats and are advancing across an international landscape of evolving capital markets, research initiatives, government regulations, and behavioral norms. Tailored and effective U.S. policy can help counter the threats, leverage new capabilities, advance American economic competitiveness, and expand national influence across the global bioeconomy. Such efforts nest across all pillars of the 2017 National Security Strategy and are necessary if the U.S. is to retain its global competitive advantage.

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## Engagements and Visits

### Domestic

#### *California*

[Amyris, Inc.](#) – Emeryville, CA

[Arcadia Bioscience, Inc.](#) – Davis, CA

[BioCurious](#) – Santa Clara, CA

[Bolt Threads, Inc.](#) – Emeryville, CA

[Monsanto Vegetable and Seed Research Headquarters](#) – Davis, CA

[Sandia National Laboratory](#) – Livermore, CA

[University of California, Davis, Seed Biotechnology Center](#) – Davis, CA

[Zymergen, Inc.](#) – Emeryville, CA

#### *District of Columbia*

[Biotechnology Innovation Organization](#) – Washington, D.C.

[United States Department of State, Bureau of East Asia and Pacific Affairs, Japan Desk](#) – Washington, D.C.

[United States Navy Research Laboratory, Center for Biomolecular Science and Engineering](#) – Washington, D.C.

#### *Fort Leslie J. McNair Engagements*

Mr. Josh Berlin, [Biocentury](#)

Dr. Diane DiEuliis, [National Defense University Center for the Study of Weapons of Mass Destruction](#)

Dr. Peter Emanuel, U.S Army [Edgewood Chemical and Biological Center](#)

Dr. Yali Friedman, Chief Editor and Publisher of the [Journal of Commercial Biotechnology](#)

Ms. Shoshana Griffith, [United States Department of Agriculture Foreign Agriculture Service](#)

Dr. Daniel Kolker, [United States Patent and Trademark Office](#)

Dr. Lisa Lee, [Walter Reed Army Institute of Research](#)

Dr. Gavin McIntyre, [Ecovative Design](#) (*teleconference*)

Dr. (Colonel) Nelson Michael, United States Army, [Walter Reed Army Institute of Research](#)

Mr. David Rejeski, Synthetic Biotechnology Expert

Dr. Justin Sanchez, Director, [Biological Technologies Office, DARPA](#)

Mr. John Souvlis, [Federal Bureau of Investigation Washington Field Officer, Weapons of Mass Destruction](#)

***Maryland***

[Emergent BioSolutions, Inc.](#) – Gaithersburg, MD  
[Montgomery College Biotechnology Program](#) – Germantown, MD  
[United States Department of Agriculture](#) – Silver Spring, MD  
[United States Environmental Protection Agency](#) – Silver Spring, MA  
[United States Food and Drug Administration](#) – Silver Spring, MD

***Massachusetts***

[Addgene](#) – Cambridge, MA  
[Ginko Bioworks, Inc.](#) – Boston, MA  
[Massachusetts Biotechnology Council](#) – Cambridge, MA  
[Takeda Pharmaceuticals, Inc.](#) – Cambridge, MA

***North Carolina***

[bioMASON, Inc.](#) – Research Triangle Park, NC  
[Humacyte, Inc.](#) – Durham, NC  
[Medicago, Inc.](#) – Durham, NC  
[North Carolina Biotechnology Center](#) – Durham, NC  
[Syngenta, Inc.](#) – Research Triangle Park, NC

**International*****Japan***

[American Chamber of Commerce Japan](#) – Tokyo  
 Green Earth Research Center, [Green Earth Institute](#) – Chiba  
[Innovation Center of NanoMedicine](#) – Kawasaki  
[Japan Bioindustry Association](#) – Tokyo  
[Japanese Agency for Medical Research & Development](#) – Tokyo  
[Japanese Ministry for Economy, Trade & Industry](#) – Tokyo  
[National Agriculture and Food Research Organization](#) – Tsukuba  
[National Institute of Agrobiological Sciences](#) – Tsukuba  
[Takeda Shonan Health Innovation Park](#) – Fujisawa  
[United States Embassy Tokyo](#) – Tokyo  
 Agricultural Attaché  
 Environment, Science, Technology & Health Section  
 Economic Affairs Section  
 Foreign Agricultural Service

## Introduction

*The ability to manipulate the genetic codes of living things will set off an unprecedented industrial convergence: farmers, doctors, drug-makers, chemical processors, computer and communications companies, energy companies, and many other commercial enterprises will be drawn into... what promises to be the largest industry in the world.*

*Juan Enriquez and Ray A. Goldberg, Harvard Business Review, March 2000*

*Our world is built on biology and once we begin to understand it, it then becomes technology.*

*Ryan Bethencourt, Chief Executive Officer, Wild Earth, Inc.*

In 1990, the U.S. Government launched the largest and most ambitious biology project ever: mapping the human genome. As significant to biology as putting a man on the moon was to physics, the goal for completion was fifteen years at a cost of two billion dollars.<sup>1</sup> Thirteen years later, the U.S. Department of Energy and National Institute of Health had led a highly successful public-private partnership across research centers in the United States, United Kingdom, Japan, France, Germany, Spain, and China to map 92% of the human genome with 99.99% accuracy.<sup>2</sup>

This initiative helped dramatically reduce the cost of human genome sequencing over the last twenty years. The first “draft” genome sequence in 1999-2000 cost ~\$300 million worldwide (of which the National Institute of Health provided 50-60%).<sup>3</sup> By 2017, commercially available techniques reduced this cost to below \$1,000.<sup>4</sup> This single metric portends groundbreaking potential for a wide variety of healthcare and quality of life applications. It also highlights a high return on government investment.

Healthcare is only one segment where technology is harnessing the building blocks of biology. Agriculture, industrial materials, energy, and advanced manufacturing also seek to capitalize the potential of molecular biology to enhance their products and services to provide paradigm-shifting solutions to complex problems.

In 2018, biotechnology is a \$106.9 billion industry with over 2,200 businesses and an *IBISWorld* estimated annual growth of 1.7% over the next five years. This growth is fueled by a wide array of product applications for expanding markets, while closely tied to the inherent risk of research and development at the frontier of science.<sup>5</sup> Biotechnology as a science, process, and industry breaks new ground each day while capital markets, regulatory frameworks, and norms of conduct adjust to a novel landscape.



Figure 1. Definitions of Genome and Biotechnology

Biotechnology inches closer to a tipping point where its impact on our daily lives could rival the development of the internet. At this tipping point, the volume of challenges will equal opportunities. Public and private sectors most adapted to meet these challenges will be best postured to harness the opportunities. Retaining U.S. competitive advantage in biotechnology is possible, but not guaranteed.

In December 2017, the Trump administration published its first National Security Strategy, which calls upon the United States to respond to growing political, economic, and military competitions around the world.<sup>6</sup> This framework of strategic competition contends that emphasizing American competitive advantage across all elements of power is necessary to secure the nation and is a prudent response to the contemporary global environment.

Over the last six months, it struck the authors of this paper how many leaders in the biotechnology space were drawn there by its outsized potential for our lives and economy over the next century. If only half their forecasts are correct, the United States cannot afford to abdicate its leadership and competitive advantage in biotechnology. Those who lead in the science and industry are positioned to draw the most benefit at the points of technological breakthrough. Such positioning is precisely the type of advantage the 2017 National Security Strategy seeks.

Biotechnology faces some unanswered questions and challenges. These include regulatory frameworks, the role of government in basic and applied research, intellectual property protections, capital markets, privacy, and international norms of conduct. American leadership in resolving these challenges will maximize the potential of biotechnology's contribution to all pillars of the National Security Strategy, while providing options for a myriad of current and future security challenges.

This paper's tailored policy recommendations, nested with the 2017 National Security Strategy, provide perspectives on how the U.S. Government can shape the landscape for national success in biotechnology. Continued American advantage is not a foregone conclusion.

## 2017 NATIONAL SECURITY STRATEGY

**PILLAR I:** Protect the American People, the Homeland, and the American Way of Life.

**PILLAR II:** Promote American Prosperity

**PILLAR III:** Preserve Peace Through Strength

**PILLAR IV:** Advance American Influence

*Figure 2. Pillars of the 2017 National Security Strategy*

## Industry Characteristics and Cross-Cutting Challenges

Biotechnology is not a single family of products or processes; simply defining the scope of the industry is challenging. The common factor is the application of technology to biology to produce something – an ear of corn, a drug, or piece of clothing. At its most fundamental level, biotechnology is about visualizing a product and using the processes and interactions of biology – as opposed to traditional chemistry and physics – to develop and manufacture.

A key component is cells' ability to duplicate. Whether combating cancer, making a vaccine, or producing masonry bricks, if you can alter a duplicating cell to deliver desired characteristics or molecules, you can *grow* a wide variety of products or ingredients that were previously *manufactured*. Viewing biotechnology through this lens of alternate or advanced manufacturing, although not all-inclusive, opens the aperture for its potential applications across broad sectors of the economy. To this point, the dominant players in biotechnology are the industries already structured to operate comfortably with biology.

The four largest biotechnology companies are biopharmaceutical companies with 72.3% of market share. The fifth – Monsanto – is an agriculture giant.<sup>7</sup> This highlights an industry trend of specialization, where the largest players' existing expertise in biology, drawn from current business practices, allows specialization in bio-specific products with high profit margins. This is in comparison to other industries, without a biology backbone, that explore biotechnology as an alternative way to produce a product with already well-defined market parameters – such as a new way to “grow” textiles.

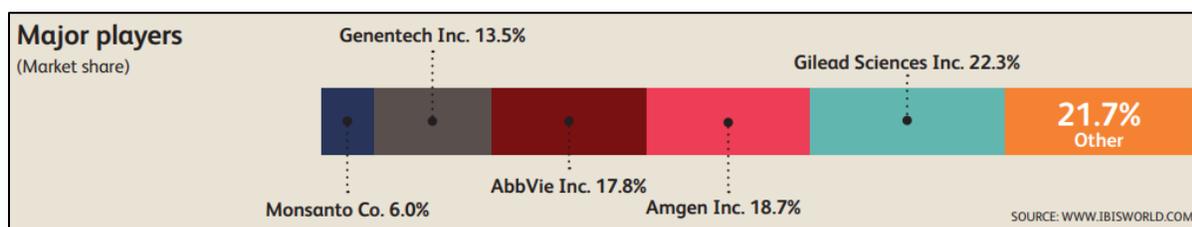


Figure 3. Major Firms in the Biotechnology Sector by Market Share

Although great potential exists across a wide range of economically significant products, pharmaceuticals will likely remain the largest biotechnology segment over the next five years due to the expanding market for drugs, increasing costs of healthcare, and an aging population.<sup>8</sup> The success of biotechnology in the highly regulated, high-cost, high-risk pharmaceutical market suggests the potential in other

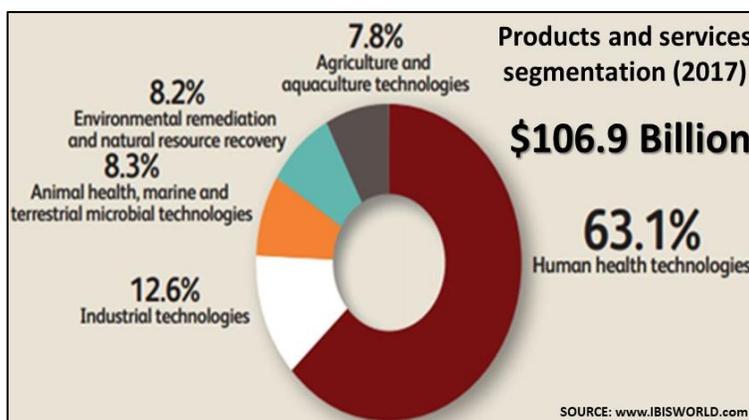


Figure 4. The Biotechnology Sector Segmented by Products and Services (2017)

industries with lower regulatory barriers. A component of this disparity is the cost and risk of biotech research and development, a landscape where the pharmaceuticals firms are adapted to operate, and where other industries are still defining their niche. For many industries, biotech research and development appear to be trying to tame the unpredictable, but as technology increasingly combines the promise of biology with the precision of chemistry and physics, barriers to entrance will erode for broad swaths of the economy.

The following model, based on Michael E. Porter's "Five Forces," demonstrates some unique – and challenging – characteristics of the biotechnology sector.<sup>9</sup>

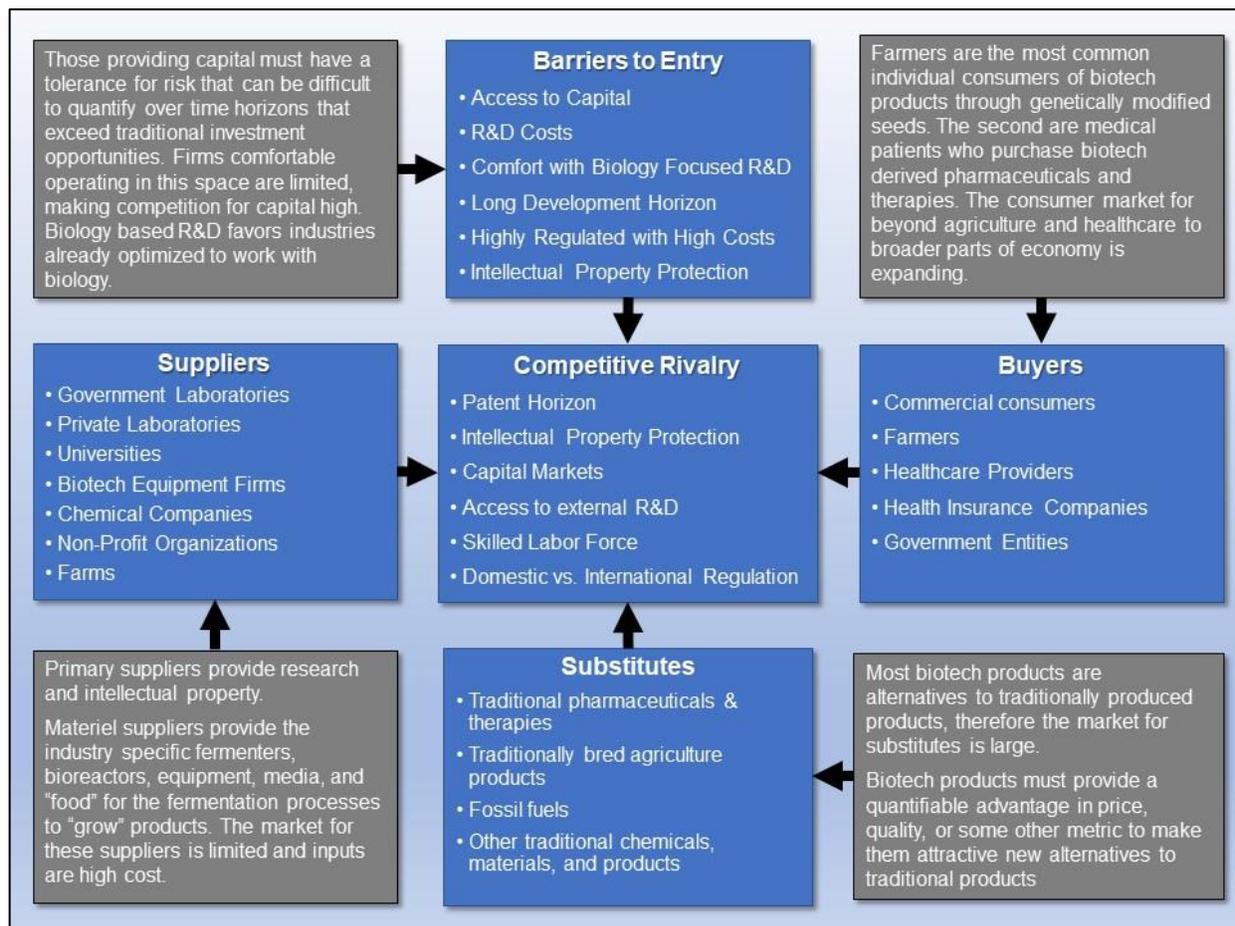


Figure 5. The U.S. Biotechnology Sector and Michael E. Porter's "Five Forces" Model

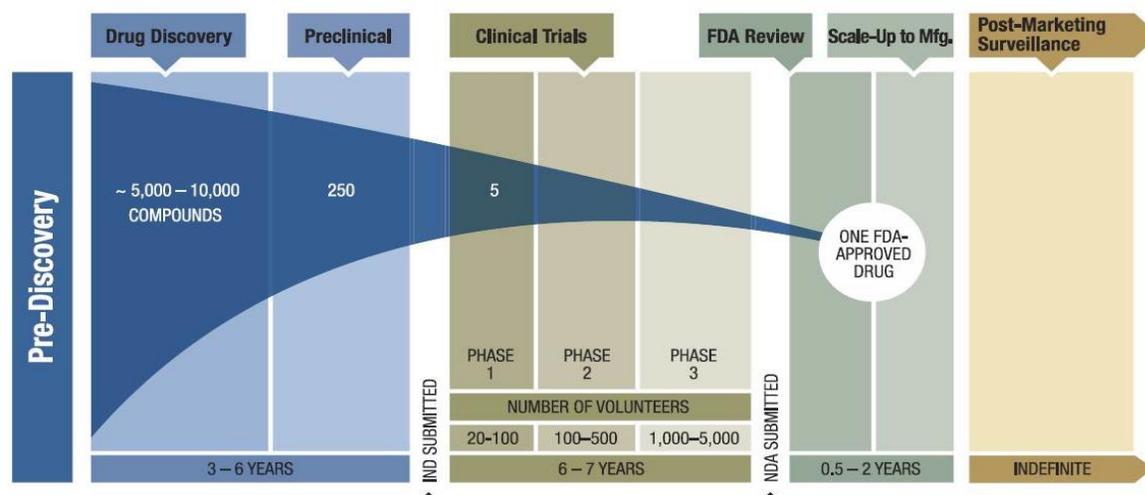
As the largest firms in the biotechnology sector, pharmaceutical and agricultural firms are typically best capitalized to fund biotechnology research and understand a biology-based research landscape. Their existing product portfolios allow distribution of risk across other activities, while maintaining the institutional knowledge to navigate a complex – and costly – regulatory framework to bring products to market through existing production capacities.

Other firms looking to enter into new markets with biotech products face these significant hurdles without an existing backbone. To compensate, many start-up firms focus on research and development with long-term aspirations to be acquired and/or license their technology to larger firms better adapted to navigate the regulatory framework and bear the burden of production costs.

This model is attractive to both capital markets and larger firms. Capital investors can mitigate risk through a portfolio strategy of multiple ventures, while maintaining equity positions for potentially large profits if a small firm is acquired or brings a product to market. Larger firms can reduce their risk by waiting until technology is proven in the start-up space, then license or acquire it as smaller firms reach their limit of technical expertise in navigating regulation.

A high start-up failure rate is the cost of this structure. In the pharmaceutical industry less than one in one hundred companies cross this “valley of death” between initial idea conception

### Drug Discovery and Development Timeline



SOURCE: American Association of Cancer Research 2011 Cancer Progress Report

Figure 6. “Valley of Death” Construct for the Pharmaceutical Industry

and regulatory approval. Industrial materials and energy products have lower regulatory burdens than pharmaceutical and agriculture products, but novel biotech products can challenge ill-adapted regulatory practices that slow products to market while increasing costs.

On the plus side, the United States’ national innovation system and evolved capital markets are the best in the world for underwriting unknowns and embracing the potential of new industry processes like biotechnology. The same structural advantages that helped create Silicon Valley have also helped the United States lead the world in biotechnology innovation and products to market over the last twenty years.

Public-private partnerships, strong intellectual property protection laws, and evolved capital markets have been the nation’s competitive advantage. Adapting future policy to foster this continued advantage across new landscapes is not only essential to the success of the biotechnology sector of the economy, but significantly enhances national security and positions the United States to address a myriad of challenges, threats, and opportunities over the next century.

## Protect the American People, the Homeland, and the American Way of Life

### *Biotechnology: Threats and Tools*

Biotechnology offers promising tools and solutions for meeting America’s national security needs. In the wrong hands, advancements can be used to threaten the American homeland and the American people. Harnessing the tools and mitigating the threats within this

fast-moving science directly support the first pillar of the National Security Strategy: Protecting the American People, the Homeland, and the American Way of Life. Emphasis in this area is growing but remains insufficient.

### Biothreats: Bioweapons and Pandemics

Many of the great biotechnology discoveries represent a dual-use threat, with immense potential for positive advancements while simultaneously providing tools such as targeted bioweapons and pathogens for those with malicious intent. As Dr. Diane DiEuliis, et al stated, “nefarious (dual) use of the tools and techniques of precision medicine could enable the creation of ‘precision maladies’ by nations or actors seeking to harm specific individuals or groups.”<sup>10</sup> Further, adversaries may pursue alteration of existing pathogens to the extent that current vaccines are rendered ineffective.<sup>11</sup> However, in most of these dual-use situations, biotechnology also offers the pathway to biodefense preparedness. The ability for the U.S. to remain at the forefront of biodefense and countermeasure research provides the opportunity to counter, in advance, potential enemy approaches while simultaneously improving the response posture against natural and evolving pathogens.<sup>12</sup>

### Biodata and CRISPR

While biothreats manifested through bioweapons and pandemics lead the security conversation, the raw material inputs and associated design and production tools are critical to understanding and assessing these threats. The foundation of modern biotechnology is biodata, the coveted raw material used for innovative discoveries, both good and malevolent (see Figure 7). Biodata is collected and catalogued at increasing rates and with improved fidelity. The expanding set of biodata parameters goes well beyond earlier iterations of DNA sequencing.<sup>13</sup> Nation states, corporations, and scientific researchers all clamor for additional biodata for novel developments and product potential.<sup>14</sup> The dramatic decrease in the cost of and access to biodata sequencing, along with the increased ability to parse the data parameters according to segments of population, has greatly increased the ability to target medicine or weapons development down to the small group or even individual level.<sup>15</sup>

#### BIODATA

Genomic data and its associated metadata, such as translated proteins and their functions.

*DiEuliis, et al, “Biodata Risks and Synthetic Biology.”*

*Figure 7. Definition of Biodata*

The value of biodata, and therefore the risk of its improper or inadequate treatment, elicit important questions. How biodata is sourced, protected, and utilized is critical to developing a coherent security approach. The general public is, by nature, the primary supplier of biodata. Given this, the approaches to extracting the data and the public’s inclination to freely provide it are concerning.<sup>16</sup> Similar to the American public’s willingness to provide other personal information in exchange for subsidized services (e.g. “free” internet email accounts), the public has demonstrated a willingness to provide biodata samples to commercial firms in exchange for genealogical tracing services.<sup>17</sup> Cumulative American biodata will afford competitors and threat actors potential advantages over the U.S. The public is generally unaware of this downstream risk when providing their biodata to third parties. Competitor nations, namely China, will leverage the accumulation of massive sets of biodata to erode U.S. competitive advantage by most effectively exploiting the biodata and emerging as the leader in tailored and targeted

bioproducts.<sup>18</sup> This same biodata affords adversaries not only the opportunity attack via targeted bioweapons and advanced pathogens, but also opportunities to corrupt biodata integrity that is increasingly relied upon for medical treatment.<sup>19</sup>

Within the scientific research community, publication, collaboration, and replication of results are bedrock principles. Immense biodata databases have been developed by accumulating legitimately acquired samples in pursuit of research. Those involved are also considered at the more liberal end of the sharing spectrum when compared to other disciplines.<sup>20</sup> For commercial enterprises, where the business model is to generate profit from the monetization of data acquired via sale of subsidized products and services, the terms and conditions imposed at the time of data acquisition provide little forward control over the ultimate end use of the biodata.<sup>21</sup> Therefore, potential bad actors enjoy ample opportunity to engage in transactions for biodata acquisition. This is especially true where these transactions are not otherwise precluded by existing systems such as the Council on Foreign Investment in the United States (CFIUS) or the currently contemplated Foreign Investment Risk Review Modernization Action (FIRMA) legislation.<sup>22</sup>

Another potential dual-use concern comes in the form of gene editing tools, namely CRISPR (see Figure 8). CRISPR advances the ability to achieve targeted cuts and insertions of DNA material into genomes.<sup>23</sup> This opens the door to exciting scientific advancements in targeted disease treatments and carries with it tremendous economic potential - which will be addressed in greater detail later in the paper - as well as creates security risks. Former Director of National Intelligence James Clapper stated, “CRISPR can both enable improved capacity to manipulate pathogens and may make such manipulations easier and quicker.”<sup>24</sup> CRISPR kits have become commercially available and relatively inexpensive, allowing everyone from academic researchers, to hobbyists, to high school students to experiment with gene editing. The novel security concern surrounding CRISPR, compared to other gene-editing techniques, is the lack of trace or sign that the process has been used. The proliferation of the tool, along with the fear that existing abilities to detect the presence of gene-editing are inadequate, has led to government-sponsored efforts, such as Safe Genes by the Defense Advanced Research Projects Agency (DARPA)<sup>25</sup> and Felix by the Intelligence Advanced Research Projects Activity (IARPA),<sup>26</sup> to develop mechanisms to identify and mitigate threats stemming from gene editing technology.

The potential benefits of biotechnology in protecting the homeland far exceed the threats. Certainly, the DARPA and IARPA programs exemplify pursuit of increased U.S. security, however, there are opportunities tied to the positive potential biotechnology affords. Although the increased utility and availability of biodata databases provide more opportunities for bad actors, it also sets conditions for more advanced biodefense capabilities. While providing the means to counter targeted bioweapons, the scientific advances also provide tools for the U.S. to improve the nation’s resiliency towards naturally occurring pathogens that could imperil the



Figure 8. Definition of CRISPR

populace.<sup>27</sup> Continued progress in the areas of biodefense and precision medicine are the roads to improving the nation's resiliency and, as is discussed later, capacity: precision medicine will have a direct impact on military health and readiness.

## **Agricultural Resiliency**

Biological threats can not only target people, but agriculture. Recognizing the importance of American agriculture, the U.S. Government designated the food and agriculture sector as critical infrastructure in 2003.<sup>28</sup> Not only is the agriculture sector essential in feeding America's people, but it is also economically significant, accounting for ~5% of the gross domestic product (GDP).<sup>29</sup> Disruption of the agriculture sector by biological threats (natural and manmade) could not only lead to food shortages, but also a significant economic impact.

Since the agriculture sector is vital to protecting the American people and their way of life, America needs to increase its resiliency in dealing with potential shocks and stresses as described in the 2017 National Security Strategy.<sup>30</sup> One way is through greater genetic diversification of crop lines. Over years of economic optimization, there has been a decrease in agricultural diversity as only the most productive lines have been retained.<sup>31</sup> This has potentially affected the agriculture sector's ability to deal with shocks and stresses. For instance, while there are roughly 250 to 300 lines of corn in existence, only six are used in America.<sup>32</sup> In 1970, the "southern corn leaf blight" struck America's corn, with approximately 90% being susceptible due to lack of genetic diversity, resulting in a 15% reduction in output (representing a \$13-21 billion loss in today's dollars).<sup>33</sup> This illustrates how utilizing a limited number of crop lines can result in lower overall resilience and impact not only food production but also economic capacity.

While focusing on crop lines with the highest yields makes sense from a purely business perspective, it does not help increase overall resilience in the agriculture sector against biological threats. Therefore, it is in America's interest to use biotechnology to increase the genetic diversification of a wide variety of crops to ensure maximum resilience. In addition to biological threats, another potential stressor to the agriculture sector is the changing climate.

Changes in the Earth's climate are likely to put increased stress on the agriculture sector in years to come. The National Climate Assessment states, "Climate disruptions to agricultural production have increased in the past 40 years and are projected to increase over the next 25 years. By mid-century and beyond, these impacts will be increasingly negative on most crops and livestock."<sup>34</sup> To mitigate effects of climate change and protect the American people from the potential resulting food shortages, it is in America's interest to utilize biotechnology as a means to develop new crop lines that can thrive in changing climate conditions.

Developing crops that can adapt to changing climate conditions will not only ensure America's agriculture sector remains vibrant but can also assist other countries. This is important since "about one-fifth of all food consumed in the U.S. is imported."<sup>35</sup> America should not only develop solutions for domestic agricultural climate change-related issues, but also find biotech crop solutions that will assist other countries in dealing with the changing climate, a topic discussed later under *Advancing American Influence*.



## **Promote American Prosperity** *The Economic Advantage of Biotechnology*

### **Promoting Innovation**

America is the world's most prosperous economy in large part due to its ability to innovate. As the world is on the precipice of a biological revolution where biotechnology drives to the forefront and may even represent a new industrial revolution, it is imperative that the federal government remain attuned and involved when and where necessary to promote opportunity. Today's ground-breaking advancements also impact U.S. national security and, if not harnessed effectively, could result in the United States losing competitive advantage over other nations.

The 2017 National Security Strategy presents the idea that our nation has experienced a departure from strength and competitive advantage and highlights the vital importance of revitalizing our position in the world,

Following the remarkable victory of free nations in the Cold War, America emerged as the lone super power with enormous advantages and momentum in the world. Success, however, bred complacency. A belief emerged, among many, that American power would be unchallenged and self-sustaining. The United States began to drift. We experienced a crisis of confidence and surrendered our advantages in key areas. As we took our political, economic, and military advantages for granted, other actors steadily implemented their long-term plans to challenge America and to advance agendas opposed to the United States, our allies, and our partners.<sup>36</sup>

This American hubris theory put forth in the Nation Security Strategy complements Linda Weiss' theory that American competitive technological advantage was achieved and is maintained by what she refers to as the National Security State. Beginning in the 1940s, the United States achieved global dominance and technological advantage by investing in basic research to support its security infrastructure.<sup>37</sup> When the Berlin Wall fell, and the United States emerged as the single superpower, it was natural that elected officials would seek a peacetime dividend and reduce funding for research as it appeared that existing technological advantages were sufficient to maintain a security advantage. However, by taking this course, United States leadership failed to heed numerous warnings that not supporting basic research would result in the atrophy of technological innovation.

Weak U.S. Government commitment to both biotech research and business development, contrasted with strong commitment and focus in China, is particularly worrisome. If the United States is to dominate in innovation and this emerging revolution to build biology into technology, policy makers must reflect on the past to determine how the United States achieved and maintained its status as the global technology leader and reengineer its processes to ensure long-term competitive advantage.

### The Basic Research Funding Crisis

Analysis of current trends in basic research offers decision makers an opportunity to subjectively understand whether the United States is on the correct glideslope, or whether modifications to federal funding or public policy should be undertaken. While a specific

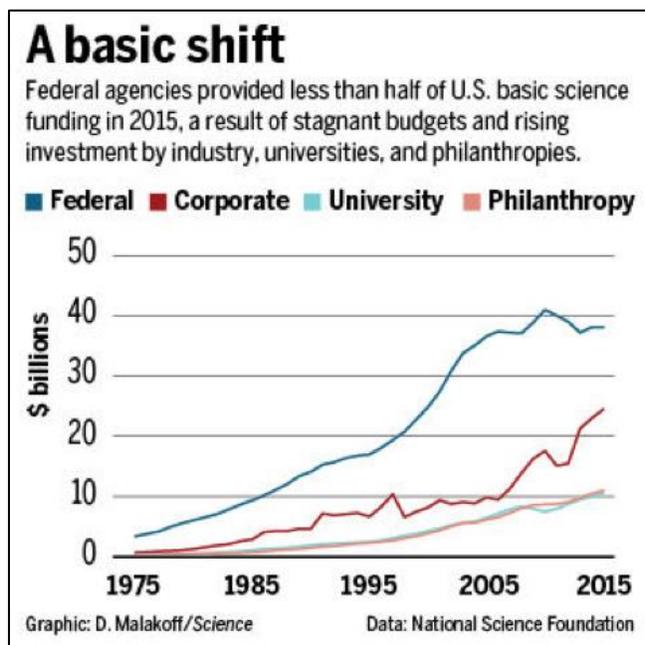


Figure 9. The Changing Role of Government Funding for Basic Research

examination of funding for biotechnology alone would seem appropriate, the sector is entirely too wide and multidisciplinary to lend itself to such analysis.

Acknowledging the fact that government-funded basic research gave rise to some of the most profitable and innovative technologies the world has seen; when compared to private and academic investment, the United States government has reduced its share of the pie for basic research over time. Although there has been a steady rise in all sources of funding, recently, there has been an uptick in corporate funding and a decrease in federal funding (see Figure 9). While it seems encouraging that the ratio of private funding appears to be increasing, it should be noted that, as Monsanto's vice president, Philip Brodsky points out, this funding is often discontinued before it produces a breakthrough technology due to stock holders' and investors' intolerance to risk and out-of-the-box thinking.<sup>38</sup> If Brodsky's assessment is correct, then basic research funding from the private sector is too subject to the whims of investors and corporate boards to be reliable, leaving government funding as the primary source of funding for basic research<sup>39</sup>.

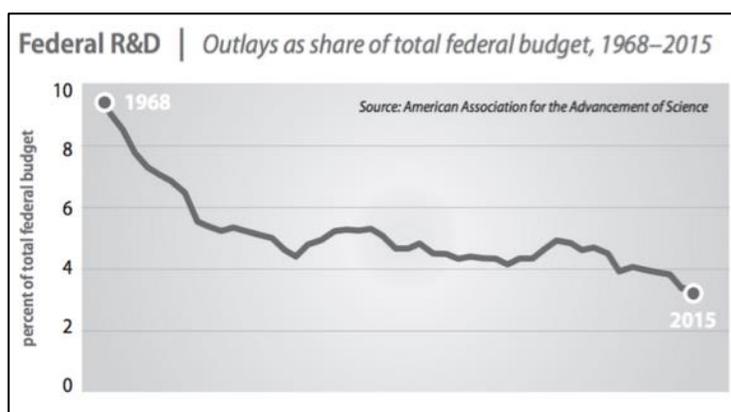


Figure 10. U.S. Federal Funding for Research and Development 1968-2015

Figure 10 demonstrates a significant reduction in government-funded research and development as compared to the federal budget over time. Prominent academic scientists throughout the United States have commented that this lack of funding for basic research threatens the nation's ability to produce ground-breaking technologies for the long term. Dr. James Tien, Distinguished Professor and Dean of the College of

Engineering at the University of Miami posits that basic research is the primary fuel for

breakthrough innovations; however, global competition and the focus of the stock market on short term gains have driven commercial entities away from basic research and toward applied research. He echoes Brodsky's concern that research in commercial institutions is often short-term and focused toward making incremental improvements to existing technologies as opposed to the development of new technologies.<sup>40</sup> Truly transformative technologies are generally a result of longer term investments in basic research.<sup>41</sup>

Government funding for basic research from 2013-2017 remained relatively flat (see Figure 11). Budget cuts to research and development have forced major interested parties, such as the former Under Secretary of Defense for Acquisition, Technology and Logistics, Frank

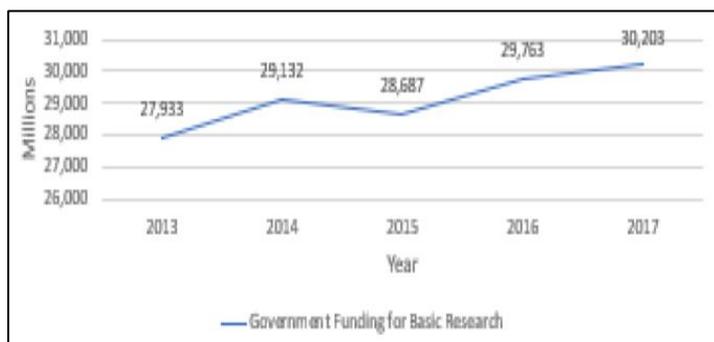


Figure 11. Flattening of Government Basic Research Funding 2013-2017

Kendall, to seek commercial off-the-shelf solutions (COTS) as a stop-gap measure to substitute for lack of new and innovative options.<sup>42</sup> Though this may have been the only reasonable means to slow the erosion of competitive scientific advantage in a time of budgetary austerity, it is ineffective in increasing or even maintaining competitive advantage.

## Protecting Innovation

### *Importance of IP in Biotechnology*

Intellectual property protection incentivizes inventors to make investments because it protects their profit potential through exclusive (usually time-limited) use of their innovations, making the high cost of research worthwhile and avoiding the perils of low cost replication by competitors. Intellectual property protection consists of patents, trade secrets, and trademarks. The efficacy of such protections is the backbone of a national system that successfully encourages innovation.

A patent prohibits others from making, using or selling the invention claimed for a period of 20 years from the date it was filed with the U.S. Patent and Trademark Office (PTO). Patents are relatively inexpensive (approximately \$10,000 in addition to a few thousand in maintenance fees), however, enforcing them can cost millions.<sup>43</sup> Considering the level of revenue for a biologic drug, for example, the cost of litigation may be well worth the investment.

The most inexpensive, yet indefinite in length of time of protection, is a trade secret. Trade secret protections, such as confidentiality or non-disclosure agreements, are designated by the organization themselves and require zero government agency review. Trade secret owners can also pursue reparation for improperly disclosed or improperly learned information through litigation, but the rewards are often substantially less than those offered by patents.<sup>44</sup>

The third category, trademarks, offer protection of “words, symbols or phrases that are used to identify a particular manufacturer or seller and their products and to distinguish them from others”.<sup>45</sup> Trademarks last indefinitely but can be lost due to abandonment if not used frequently.

A recent positive development for intellectual property protection for biotech companies is the Food and Drug Administration’s (FDA) enhanced protection of data from clinical trials. Originally, companies developing new drugs and agricultural protection products were able to protect data from their clinical trials for a period of five years. Due to the ease with which one could create a “biosimilar” medicine or agricultural product that may not be covered in the scope of the patent, Congress authorized provisions in the Affordable Care Act to extend data protection rights for a period of twelve years following FDA approval.<sup>46</sup> This extended protection is deemed as “necessary to ensure biopharmaceutical innovators and the associated global scientific eco-system are able to sustainably pursue groundbreaking biomedical research.”<sup>47</sup> While this is particularly good for U.S. companies operating within the United States, it would be globally beneficial if trading partners overseas also adopted similar data protection regulations. Such an adoption would fall within the World Trade Organization (WTO) rules that “require parties to protect regulatory test data against both disclosure and unfair commercial use.”<sup>48</sup>

### ***Chinese Biotech IP Landscape, Concerns, and Efforts***

Concerns regarding U.S./China trade relations appear in the newspaper headlines daily. Intellectual property protection is one of the primary issues at the center of the debate. As the world’s most populous nation continues to grow, its food, health, and energy needs increase. Biotechnology offers potential solutions in each of these realms. China’s latest five-year plan, “stipulates that the biotechnology sector should exceed 4% of gross domestic product by 2020 and... there should be 10 to 20 life-science parks for biomedicine with output surpassing 10 billion yuan (U.S. \$1.5 billion).”<sup>49</sup> Measuring the competition for biotechnology IP between the U.S. and China, the U.S. currently holds the largest number of biotechnology patents overall, but the lead is quickly decreasing. Mr. Ron Cohen, President and CEO of Acorda Therapeutics pointed out in his 2012 Congressional testimony that China and India are currently ranked number one and number two in terms of *new* biotechnology patents, with the United States ranking twentieth worldwide.<sup>50</sup> When measuring the headquarters location of the top fifty patent assignees, as one would guess, the U.S. had the highest number of patent seekers, but new applications only increased by 7.31% from 2015 to 2016. China came in sixth but experienced a 158% increase from 2015 to 2016.<sup>51</sup>

Biotechnology and innovation within China are not necessarily negative but the pairing with unfair practices, policies, and regulations that discriminate against foreign investment, preclude foreign commercial operations, and violate intellectual property rights, creates problems. A 2011 United States International Trade Commission report indicated that if China strengthened its intellectual property rights protection to a level comparable to the United States, an estimated \$107 billion could be gained in U.S. exports and sales to affiliates.<sup>52</sup> In August 2017, President Trump sent a Presidential Memorandum to the United States Trade

Representative asking him to, in accordance with the Trade Act of 1974, “investigate any of China’s laws, policies, practices, or actions that may be unreasonable or discriminatory and that may be harming American intellectual property rights, innovation, or technology development.”<sup>53</sup> U.S. Trade Representative Robert Lighthizer responded in a press release that he did in fact find critical issues that warranted an investigation under Section 301 of the Trade Act of 1974.<sup>54</sup>

Prior to President Trump, President Obama’s administration also took steps to address the U.S. – China intellectual property dispute. In 2008, under the Prioritizing Resources and Organization for Intellectual Property Act, Congress created an Intellectual Property Enforcement Coordinator (IPEC) within the Executive Office of the President overseeing two separate interagency committees “in order to develop and implement the U.S. Government’s IP enforcement priorities.”<sup>55</sup> Under the law passed by Congress, the IPEC is required to report annually on the “progress made towards the effective enforcement of IP rights,” and every three years develop and deliver a “Joint Strategic Plan on IP Enforcement.”<sup>56</sup>

The strategic plan, which was recently published in 2016, addresses current IP issues, improvements to domestic IP rights, cooperation with foreign governments, use of trade tools, and voluntary private-sector best practices. There is no direct mention of biotechnology per-se, but the document does discuss counterfeit pharmaceutical drugs and the associated threat to national security since many of the counterfeit producers are also tied to organized crime and terrorist activities. Continuing to strengthen the country’s ability to protect our intellectual property will be critical to maintaining our global advantage.

### **Creating Conditions for Economic Advantage**

Typically, in biotech, a technology is developed by a startup company, then the company must find an angel or capital investor to provide funding for further development. If this is achieved, even further investment by a venture capitalist is necessary to develop the technology and get it to market. However, most startups do not get past the development stage, and end up falling into the proverbial ‘valley of death,’ where they never overcome funding challenges and their product never makes it to market. This is where government, at all levels, can make the biggest difference.

City, county, state, and private biotechnology clusters and organizations have formed for the sole purpose of bridging these gaps and advancing biotechnology commercialization and business. One such organization is the North Carolina Biotechnology Center (NCBiotech), whose mission is to, “accelerate life science technology-based economic development through innovation, commercialization, education and business growth.”<sup>57</sup> As a primarily state-funded organization, NCBiotech acts as a facilitator and promoter for the \$86 billion in economic activity, employing over 63,000 North Carolinians, creating more than \$2.2 billion in state and local taxes.<sup>58</sup> At the local level, attracting investment in new technologies is often a major challenge. Municipalities such as Prince William County, Virginia are providing incentives for investors in biotech. Christopher Girdwood, Prince William County Science Accelerator

Business Development Manager, stated that “with the tax breaks, angel investors would come bet on a company and pick up a little equity along the way”.<sup>59</sup>

To help spur general investment and innovation at the federal level, in 2016, Congress expanded Section 1202 of the Internal Revenue Code providing significant tax benefits to angel investors and entrepreneurs.<sup>60</sup> Under the current code, investors can receive up to a 100% tax break on capital-gains in qualified investments, albeit with restrictions. The investment must be held for five years and may not be in the service, finance, farming, mining, extraction, restaurant, hospitality, or real estate industries.<sup>61</sup> Biotech covers a wide array of these businesses and is significantly impacted by this investment restriction. Adjusting the code to include biotechnology would promote more investment in startup companies to allow ingenuity to develop from idea to product.

Known as “America’s Seed Funds,” the National Institutes of Health (NIH) startup funding programs such as Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) are great examples of federal funds attempting to lower the financial barrier to entry, but finances are not the only impediment. Small startups generally include researchers who lack the business expertise to succeed in industry. Local, state, and private biotechnology promotion organizations fill this important gap. National level support, involvement, and acknowledgement of these valuable organizations would create a high return on investment.

Another challenge at the ground level of biotechnology innovation is the high price of laboratory equipment and workspace. Within the biotech ecosystem, organizations and governments are increasingly making available equipment and space to researchers at an affordable, often ‘co-op’ price. Providing facilities physically located with academic institutions, combined with affordable community lab space and economic consulting to assist scientists in navigating the ‘valley,’ leads to much more efficient and effective development of biotechnology innovation. Biotechnology clusters associated with bioscience academic institutions throughout the United States can set the conditions for the U.S. to maintain a competitive advantage in the industry.

### **American Innovation – CRISPR**

American innovation led to one of the most transformative developments in the biotechnology world, CRISPR, which allows a cross-section of industry to cut sequences of unwanted DNA to produce better products, at a cheaper cost, and much more efficiently than ever before. This gene editing technology has only been around for a few years and it has already revolutionized the biotech sector. The potential applications and impact of this rapidly evolving technology are immeasurable, and the interest and investments in gene editing suggest large potential societal and economic benefits. Market research indicates that the global gene editing market is expected to reach \$6.28 billion by 2022, a compound annual growth rate of 14.5%.<sup>62</sup>

CRISPR has the potential to improve health by preventing, treating, and even curing a wide array of diseases. Scientists are finding a wide range of applications for the technology including ameliorating the disease symptoms of diabetes, muscular dystrophy, and acute kidney

disease as well as making animal organs suitable for human transplantation.<sup>34</sup> With the nation's aging population, it is expected the cost of healthcare will rise faster than the economy in the future. According to a 2018 Center for Medicare and Medicaid Services report, healthcare spending is expected to increase 5.5% annually through 2026, which is 1% percent faster than the economic growth projections.<sup>33</sup> The increase in healthcare costs will contribute to the rise in the national debt and crowd out investments in education, research, infrastructure, and national security. CRISPR offers the prospect of meeting future health care needs more cheaply and effectively.

CRISPR also offers the opportunity to grow crops that produce higher yields, are resistant to disease, and can adapt to low water conditions. The low price and accessibility of CRISPR make it a sustainable option to diminish the malnourished population in areas that struggle with food security, like parts of Africa. This technology could eradicate diseases that plague livestock and thus provide food security and economic growth to the region. In the next 30 years, the population of 26 African countries is projected to double.<sup>37</sup> In light of the increasing global population and climate change, CRISPR could help avert a global food crisis with its potential to improve both animal and plant products. However, a leading priority must be to address the regulatory uncertainty regarding gene edited products in the U.S. and abroad to avoid situations such as the \$2.9 billion U.S. market disruption caused by China's 2014 refusal to import U.S. corn containing traces of Syngenta's genetically modified corn strain.<sup>38</sup> By laying the proper foundation, the U.S. can leverage CRISPR to ensure global food security, improve world health, and strengthen the U.S. economy.

### **American Innovation – Bio-Energy**

The 2017 National Security Strategy states that America will embrace its energy dominance because unleashing abundant energy resources stimulates our economy.<sup>63</sup> Although this statement is directly addressing increasing shale oil and natural gas production, biotechnology can offer multiple other options to diversify the energy sector to eliminate any significant and detrimental impacts of reliance on any one product while promoting national energy independence.

With biotechnology innovations such as CRISPR, the likelihood increases of alternative energy sources such as algae, a third-generation biofuel, as a drop-in fuel. Prior to CRISPR, algae produced energy in the form of lipids when starved of nitrogen. This process stunted the growth of the algae and negated any other potential byproducts. Since the discovery of CRISPR, the most recent technological breakthrough in microalgae biofuel research was that a partnership between Exxon Mobil and Synthetic Genomics was able to gene edit an algae strain that doubled lipid yield without stunting the growth of the algae, resulting in increased energy output and offering the potential for other biomass product use and innovation.<sup>64</sup>

The focus and attention alternative fuel research garners typically follows periods of crisis: the oil crisis in the 1970s and skyrocketing oil prices in the 2000s are two of the most prominent examples. Historically, when oil prices rise above acceptable levels in the market, the call for research of alternative fuel sources is intense, quick, loud, and full of promise but

ultimately only akin to a short-term distraction. As crude oil prices fall, the demand for such alternative sources wanes. Unfortunately, as today's oil prices steadily creep higher, many of the biofuel startups that were born during the last oil spike have already either died off or moved on to other more lucrative products. Neither public demand nor government regulation has been consistent enough to provide industry with confidence in pursuing alternative fuels. Short-term economic perspectives ignore the important national security imperative of weening America off its oil-reliance, a factor which often dictates foreign policy decisions and leads to complicated U.S. relationships and entanglements, particularly in the Middle East. The quest for alternative fuels and for America to ensure its own long-lasting energy independence and security should be adequately prioritized at the federal level to drive the development of a diverse portfolio of affordable biofuels. By utilizing advances in biotechnology such as CRISPR, the U.S. can enjoy national security advantages while furthering America's long-term economic prosperity well into the future.



## **Preserve Peace Through Strength** *Biotechnology's Contribution to the Military Dimension*

Harnessing the power of biology complements similar efforts to leverage manufacturing, computing, and automation as transformational military capabilities addressed specifically in the 2017 National Security Strategy.<sup>65</sup> When integrated with engineering and scientific disciplines such as chemistry and physics, biology represents asymmetric potential to address current and future environments and improve the capacity, readiness, and modernization of the United States military.<sup>66</sup> Advances in medicine fueled by biotechnology will provide the nation with abilities to overcome medical challenges of forces currently restricted from deploying, as well as those of the potential recruits for the future. On the readiness front, biotechnology offers significant capability to address logistical sustainment challenges associated with operations in austere, denied environments. Finally, with respect to modernization, advances in biotechnology will provide significant updates to battlefield medicine capability, allowing DOD to field 21<sup>st</sup> century medical capability alongside its 21<sup>st</sup> century fighting forces.

### **Capacity**

The United States' all-volunteer military relies on the capacity of the nation to provide sufficient personnel to meet the requirements of a wide range of contingencies. This capacity hinges on two variables: the ability of members of the U.S. population to meet entrance standards, and the ability of current military personnel to meet operational requirements. Biotechnology offers promise in helping maximize those necessary abilities in both populations.

Despite advances in diet and medicine, obesity in the U.S. is trending upwards, especially in youths sixteen to nineteen years of age, a prime demographic of those considering military service. Currently, one in five children in the U.S. is obese.<sup>67</sup> Perhaps even more concerning, in a study conducted between 2007 and 2008, more than five million males and sixteen million

females of military age exceeded the U.S. Army's height/weight standards.<sup>68</sup> Obesity can originate from multiple factors, including behaviors and genetics, but advances in precision medicine powered by biotechnology can clarify and target the interactions between those factors and contribute to the future prevention and treatment of obesity.

Obesity and its related health issues are not just a concern for the pool of potential recruits. In a 2012 report, the Centers for Disease Control noted that in the last fifteen years obesity rose by 61% among U.S. service members.<sup>69</sup> As of 2017, 78,000 members of the active duty Army (or 15%) were found to be clinically obese with a body mass index above 30%. These Soldiers are also at a higher risk for obesity-related conditions, rendering them 36-86% less likely to deploy, and increasing DOD healthcare cost by 1.5 billion dollars annually.<sup>70,71</sup> Each of these metrics represents a significant impact on DOD capacity to meet security challenges.

Based on recent advances in genomic discovery, investment in biotechnology and an enabling regulatory framework could improve overall DOD personnel health readiness by increasing the fidelity of disease detection and optimizing risk management. Genetic sequencing and the identification of disease and other molecular biomarkers will become the future tools of prediction, prevention, and treatment for diseases that significantly impact capacity. Besides obesity, post-traumatic stress disorder is also a disease that could benefit from greater biotechnology-enabled understanding of human systems.

Using genetic information to predict disease for even highly penetrant genetic variants remains a complex and emerging science. The intersection of millions of genetic variants and data obtained from wearables, electronic health records, social media, telemedicine, medical bills and other environmental exposure information presents a significantly complex landscape and biodata set. The future challenge of applying biotechnology to medicine will be to navigate this landscape to deduce actual phenotype expression of disease and accurately reproduce actionable information for medical decision makers. Genetic biomarkers may be used to preemptively determine at-risk populations and the DOD is poised to be at the forefront of genomic research, with multiple studies currently being conducted by the Army, Air Force, and Navy.

The DOD has a unique structure for linking biological molecular research and medicine:

- Military Health System (MHS) with hundreds of clinics worldwide
- Single health insurance that covers the lifespan of service members
- Single electronic medical records system for 9.4 million beneficiaries
- Single database for environmental information
- Service-level personnel databases able to leverage social and environmental information

Linked together, these systems provide a unique platform for the future of genomic medicine and provide the necessary data points for longitudinal studies that can explore the role of specific exposures, the environment, and genetics on diseases of military significance.

Finally, research studies that focus on the interaction between genes, lifestyle, and the environment are important for the future of military performance. However, civilian-centered data

and research will not always include variables of interest to a military population. Specialized mission sets, training, demographics, and worldwide presence place an added burden on the health and wellness of service members, meaning that the DOD needs to take the lead on pursuing genomic discoveries that provide new avenues to effectively target, prevent, and treat diseases of military interest.

## Readiness

6,200 and 5,200 nautical miles – these are the respective distances between San Diego, California to Okinawa, Japan and Seattle, WA to Seoul, South Korea. Both U.S. cities are home to the major U.S. Marine Corps and Army forces responsible for supporting any future conflicts in the Pacific theater, and Okinawa and Seoul are expected forward staging bases for the U.S. forces. Aggravating this already significant distance challenge is the fact that, for the last 2,000 nautical miles of transit to those staging bases, any air or sea asset faces a potential threat from anti-access and area-denial (A2AD) weapon systems.<sup>72</sup> Further complicating the planning for any future conflict is the assumption that those same main overseas bases to which the Marines and Soldiers would deploy would also be targeted. One option to increase the survivability of the deployed Marines and Soldiers is to disperse them throughout the Pacific on various islands. Sustaining this multitude of locations under the threat of an A2AD environment creates a logistical support problem that requires a new conceptual approach.

The improving lethality and range of our adversary's strike capability means that the U.S. can no longer rely upon large bases to provide "hub and spoke" logistical support in future conflict environments. This problem is intensified by the extended air and sea lines of communication present in the Pacific theater. Biotechnology can become a key enabler in reducing the logistical requirements for future conflicts by providing deployed forces with the ability to grow a portion of their food and fuel at their forward locations.

Advances in academic, commercial, and government research and development have transitioned such sustainment technologies from the potential to the possible. The following capabilities, based on current science, can provide the U.S. a competitive advantage in future conflicts by reducing sustainment requirements.

### *Food*

Within the last few years, there have been several advances in genetic editing technology, of which the most promising is the previously discussed CRISPR. This technology offers significant potential for specialized produce crops, specifically in optimized genetic traits and increased yields. To capitalize on this, DOD should seek to incentivize the development of crops that can thrive in deployed environments. However, produce crops alone are not sufficiently calorie dense to sustain deployed personnel at sufficient levels. Fortunately, recent advances in growing proteins now offer a path to a viable solution. Several companies recently developed technologies that allow the generation of meat protein (livestock, fowl, fish) grown in a cell culture.<sup>73</sup> While the current cost of producing this protein is high at approximately \$2,400 a pound, predicted advances in the process are expected to lower the cost to around \$5 per pound.<sup>74</sup> Using gene editing to create higher yield cell cultures, lower cost growth mediums for

the cultures, and more efficient production techniques are all on the near horizon.<sup>75</sup> According to an analysis at the Wageningen University in the Netherlands, with these advances a single 10,000-gallon tank can produce enough protein to feed over 2,500 people.<sup>76</sup>

### ***Fuel***

A 2006 MITRE Corporation analysis estimated that fuel delivery to the front lines costs DOD between \$100-\$600 per gallon.<sup>77</sup> Between cost and the lives and equipment placed at risk to deliver the fuel, there is significant future benefit to finding alternate means of supplying fuel to deployed troops. As covered in the previous chapter, algal-based biofuels are a likely contender to meet this need. The Department of Energy estimates that algae can be 10 to 100 times more productive than traditional biofuel feedstocks.<sup>78</sup> Unfortunately, the current cost and yield associated with generating algae-produced fuel is prohibitive for use in a deployed environment. Fortunately, incorporating the recent introduction of low-cost and efficient gene editing techniques into producing algal biofuels brings the concept of creating fuel near the front lines closer to reality.

### ***Waste Management***

Waste management is a significant challenge to units operating in austere and expeditionary environments. The combination of human, paper, plastic, and food waste quickly stockpiles at these deployed sites, creating multiple hazards. Burning or burying waste, which are the current standard options for disposal, creates further health and environmental hazards.<sup>79</sup> Biotechnology provides another option, one that brings with it the benefit of using waste to generate electricity. In 2009, the U.S. Army tested a prototype Tactical Garbage to Energy Refinery (TGER) as a proof of concept.<sup>80</sup> The experiment converted the dry and wet waste into feedstock for a hybrid thermochemical and biocatalytic reaction, and test results showed expeditionary sites can both reduce waste and produce energy with biotechnology.<sup>81</sup>

## **Modernization**

As with expeditionary deployment and sustainment, the issue of time and distance is extremely important to battlefield medicine. In trauma medicine, the first hour after initial injury is known as “the golden hour” because survival rates increase dramatically when appropriate medical care is rendered within an hour.<sup>82</sup> Disease also historically challenges expeditionary forces. Prior to World War II, more U.S. service members died of disease during combat than battlefield injury.<sup>83</sup> Advances in immunizations and antibiotics are the primary reasons for the decline in disease-related deaths.<sup>84</sup>

Biotechnology potentially offers significant capability increases in both trauma medicine and disease control and prevention, especially in austere and/or denied environments. As an example, DARPA recently instituted a program known as Biostasis. While a Broad Agency Announcement (BAA) for Biostasis is not yet available to provide more significant details, the program seeks to “[extend] the golden hour, not by improving logistics or battlefield care, but by going after time itself, at least how the body manages it.”<sup>85</sup> The program seeks technologies to

slow the human biological process by manipulating cellular metabolic reactions in a way that is easily reversible once the wounded individual reaches a treatment facility.

In addition to Biostasis, DARPA also has projects known as Battlefield Medicine and Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) that both seek biotech solutions to the other historically devastating battlefield issue: disease and toxins. U.S. air and logistical superiority has made treatment and evacuation for such issues readily available in recent conflicts but facing a peer adversary promises to challenge that superiority.

Finally, biology also offers significant benefits to multidisciplinary approaches for solving modernization challenges in other material areas such corrosion/materials degradation, an issue that costs DOD nearly \$23 billion a year.<sup>86</sup> Along those lines, DARPA is shepherding the Advanced Tools and Capabilities for Generalizable Platforms (ATCG) and 1000 Molecules programs under the Living Foundries initiative. ATCG seeks to “[leverage] biology to solve challenges associated with production of new materials, novel capabilities, fuel and medicines.”<sup>87</sup> 1000 Molecules is intended to “enable transformative and currently inaccessible projects to develop advanced chemicals, materials, sensing capabilities, and therapeutics.”<sup>88</sup> Both programs are designed to provide innovative problem-solving tools and capability databases that will provide the basis for future problem solvers to attack tomorrow’s challenges.

Biotechnology’s intersection with national security is very clear when viewed through the lens of improving military capability. Continued DOD exploration of biotechnology promises to provide multiple capabilities supporting the National Security Strategy charge to “improve existing systems to maximize returns on prior investments...and seek new capabilities that create clear advantages.”<sup>89</sup> The U.S. must ensure it has coherent policy and regulatory frameworks to maximize the capacity of invention and innovation in this exciting field, and meet the Chairman of the Joint Chiefs of Staff’s charge to “keep pace with the speed of war” in a “unpredictable, dangerous and unforgiving” security situation.



## **Advance American Influence** *America’s Global Leadership in Biotechnology*

The transformative potential of biotechnology provides opportunities for the U.S. to solidify its leadership across the community of nations in this rapidly evolving landscape of new technology, trade, and security. Through deepening collaboration in the science and industry of biotechnology with partners and allies, capitalizing on new technologies, and shaping norms of behavior to prevent exploitation by malevolent actors, the U.S. has a unique opportunity to strengthen its global influence at the leading edge of this sector.

Targeted collaboration with partners and allies to enable the growth of global biotech sectors advances American influence in an industry primed to offer outsized economic opportunity over the next century. A strategic approach will set conditions for long-term equitable relationships in the sector, while promoting fair biotech markets and high potential growth opportunities for developing partners. The U.S. strategy should dictate that the government modernize its development finance tools to incentivize U.S. firms to invest in

biotechnology in developing countries. If properly executed, this strategy will open new markets for American industries and investments which again contributes to the advancement of U.S. influence. More importantly, by fostering this type of goodwill, it can provide additional stability by using biotechnology for the betterment of humanity.

### **Biotechnology Investment for the Developing World**

Well-crafted international agreements help establish equitable frameworks for the growing bioeconomy. More specifically, trade agreements can help gain market access for U.S. biotech manufacturers, including, but not limited to, pharmaceuticals and agricultural products. The economic value of such agreements can help break down traditional taboos regarding items such as genetically modified food, which has limited agricultural production potential for many developing nations. Robert Paarlberg, an Associate at Harvard's Weatherhead Center for International Affairs postulates that many of the world's poorest people are negatively impacted by Western attitudes toward genetically modified food. According to Paarlberg, Western nations, particularly European nations, where food is abundant reject the use of genetically modified foods because they provide no tangible benefit to the consumer, only seemingly to the producer. Because developing countries often embrace the Western aversion to genetically modified food, their unique challenges cannot be adequately addressed. Consequently, famine and food shortages can lead to the development of criminal and terrorist organizations that capitalize on local government not adequately providing for its population.<sup>90</sup> Previously discussed methods of using biotechnology through genetically modified food to enhance agriculture resiliency to climate change can also increase food security in poorer nations through increased yield, drought tolerance, insect and fungi resistance.

The U.S. can use its influence to support regional security. An example is the U.S. relationship with Nigeria, the U.S.'s largest African trading partner. Nigeria is prone to drought and plant diseases that greatly reduce crop yield and create challenges in terms of food security. Boko Haram, an extremist terrorist organization, takes advantage of food scarcity to attract recruits by providing food and life-sustaining amenities. This often develops into a binary situation where citizens must choose either to live honorably and die of starvation - or join a terrorist group and receive access to food.<sup>91</sup> Through targeted trade agreements and additional investment, the U.S. can not only increase food productivity through biotech but have a secondary effect of taking arrows out of criminal and terrorist quivers.

Leveraging U.S. influence to expanded agriculture capability could help the governments of developing nations better care for their people by improving crop yields, increasing food security, and reducing reliance on terrorist groups to provide basic goods and services. Such actions build the legitimacy of the foreign government as well as the legitimacy of the partnership with the U.S. Such efforts support mutually beneficial partnership and expanding U.S. influence within the vein of the National Security Strategy.

### **Capitalize on New Technologies and Lead International Norms**

The 1990s U.S.-led multinational Human Genome Project (HGP) not only increased knowledge of the human genome, but it also opened the door to the development of additional biotechnologies by which genetic disease could be identified and potentially cured. Through American influence, HGP unleashed the collective power of multiple nations, proving the

importance of international collaboration for scientific discovery. Though the HGP has provided scientists, pharmaceutical and biotechnological firms, and medical professionals with discoveries that have transformed medical intervention in recent years, it did not come without concerns. A major concern raised by HGP is the use of resultant genetic information and potential genetic discrimination. This and other concerns led to the adoption of UNESCO's Universal Declaration on the Human Genome and Human Rights.<sup>92</sup>

Since the completion of the HGP, newer technologies have emerged that not only describe the general human genome but can provide individual genetic profiles. In recently years the practice of collecting and cataloging human genetic data has raised concerns.<sup>93</sup> Transformative technologies such as CRISPR have opened doors to the development of cures for genetic disorders through gene editing.<sup>94</sup> The development of new technologies amidst these concerns calls for the U.S. Government to expand its influence by leading the development of international policies side by side with members of the international community in organizations such as UNESCO. This is to ensure American values of freedom, privacy and non-discrimination are applied to emerging international agreements to promote greater international cooperation in the development and implementation of policies and procedures that promise to change the global landscape in terms of medical discovery. These emerging technologies provide an opportunity for the U.S. to expand its primacy. Collaborating and sharing new biotechnological advances and innovations with allies and partners (especially in developing nations) not only directly improve quality of life through better health, food security, and countering of pandemics and diseases, but will also ensure the U.S. remains engaged at the forefront of establishing international norms for their use. This not only ensures U.S. influence in the bioeconomy, but hedges against multiple threats in how the norms of this economy develops.

### **Global Partnerships to Combat Global Challenges**

The U.S. already has an energetic biotechnology ecosystem from which to create greater influence. By utilizing national labs and academic institutions, stronger international cooperative ventures can be formed with similar institutions specifically targeting developing countries. Cooperative actions such as these would open the possibilities of bringing new technologies to emerging countries that would both improve the quality of life for millions of people and create new markets for biotechnological products in these countries. By cooperating with the International Development Organization and other non-governmental organizations, the U.S. could more easily address pandemics in developing nations using emergent biotechnological processes. The power of leveraging these technologies was demonstrated just four years ago during the Ebola outbreak. The U.S. was able to capitalize on biotechnological innovations to address the outbreak and reduce the possibility of a worldwide pandemic.<sup>95</sup>

The U.S. could establish biotechnological centers throughout the developing world, modeled after existing U.S. Navy and U.S. Army overseas research laboratories, that could serve as response centers for pandemics, allowing for the treatment of deadly diseases at their source, reducing the probability of worldwide contagion. Diplomatic and academic collaboration between the U.S. and target countries creates new partners, and potentially opens new markets for U.S. biotechnology and other products. These actions would strengthen developing governments and their response to disease while building strong and enduring relationships with the U.S.

In addition to establishing pandemic response centers, the U.S. may, through the International Development Organization, support the establishment of do-it-yourself biotechnology centers throughout the developing world. Providing an example of proper governance, the U.S. can influence greater education in biotechnology, increase diversity in academic creativity, encourage the development of biotech innovations that will improve quality of life. Furthermore, there can be increased collaboration with similar labs in the U.S. to build long-lasting relationships that may lead to future scientific discovery. The U.S. may use this platform to introduce emerging partners to powerful bioinformatic tools such as big data, augmented intelligence, machine learning, sensors, and block chain, providing a way to push the bounds of biotechnology in developing countries. The resultant collaboration would solidify ties between U.S. academic institutions and national labs with their counterparts in developing countries, increasing U.S. influence through academic, technical, and scientific interaction.

The U.S. can advance its influence within biotech by partnering with other nations seeking to enhance, or even create their own biotechnology industries, thereby increasing potential scientific discovery and applications, as well as building relations. The U.S. can work with partners to help create biotech centers emulating U.S. clusters through the synergy of: government departments and agencies, leading universities and research centers, and a responsive venture capital and angel investor community. These centers could catalyze the links between government, academic, and business, as well as attract regional investors or multi-national companies in the industry. This model would help to spread U.S. influence over norms, processes, and regulations in the development of the biotechnology sector globally and help build biotech solutions to global challenges and security while enforcing a network of positive partnerships forged through science.



## Recommendations

To achieve the National Security Strategy goal of “an America that is safe, prosperous, and free at home. . . with the strength, confidence, and will to lead abroad,”<sup>96</sup> we must use all tools of national power to continue to build and maintain America’s competitive advantage. There is great potential in the field of biotechnology, cutting across all areas of industry, particularly health care, agriculture, industrial materials, and energy. But the biotechnology sector must contend with several major hurdles inherent in its industrial structure to realize its potential. At the same time, for the U.S. to retain its global competitive advantage and optimize the contribution of biotech to national security, the government needs to play an active and decisive role in moving the biotechnology industry to maturation before the window of opportunity to lead is closed. If we are to make the most of biotechnology, we must protect, facilitate, and support our national industry.

### RECOMMENDATION GOALS

- Protect IP.
- Promote education.
- Share information.
- Enhance the economic environment.
- Protect competitive advantage.

### TO

- Protect the Nation.
- Promote innovation.
- Expand influence.

*Figure 12. Policy Recommendations:*

## Protect

One of the key roles of government in an economy and in the realm of national security is to protect the nation and its assets. Protections for innovation spur growth and development by providing incentives for researchers to break new ground and further develop the biotechnology industry. Protecting our discoveries and assets from acquisition by rivals maintains our competitive advantage. Lack of protections for biodata and innovative scientific developments would have multiple negative repercussions for the country. Not only can our security be compromised by rivals gaining access to sensitive information, but we also lose commercial advantage.

It is essential that we broaden IP protections to incentivize innovation. We should encourage international expansion of private organizations such as the industry group BIO; support international relationships among community labs; and encourage participation in international conferences and challenge competitions related to biotech. We could also expand publicly available resources to counter IP infringement and continue to implement the Joint Strategic Plan on IP Enforcement.

We must also ensure protection of U.S. biotech assets including biodata, companies, and infrastructure. The U.S. should expand the reach of CFIUS and invest in appropriate cyber security protection. We should fully utilize existing tools such as the U.S. Trade Representative's special Section 301 authority and the office of the "IP Czar" and associated committees within the Executive Branch. The government must also be sure to level the playing field so that small startups are free to innovate and compete against large commercial interests. Including innovative fuel products, such as algae-based biofuels, in the Renewable Fuel Standards umbrella for fuel blends and adding algae in the current Farm Bill to provide crop protection for farmers, could help remove barriers to entry for small biofuels producers. Similarly, continuing to fight for open markets for genetically modified or edited products globally is essential to the future health of agricultural business.

### PROTECT

- Broaden and harden intellectual property protections.
- Expand publicly available resource to combat IP infringement.
- Continue Joint Strategic Plan on IP enforcement.
- Ensure CFIUS properly address biotech competitive advantage.
- Fully utilize U.S. Trade Representative's special Section 301 and office of "IP Czar".
- Protect market access for start-up companies, new technology, and innovation.
- Protect biodata and key infrastructure.

*Figure 13. Policy Recommendations: Protect*

## Facilitate

If we aspire to retain the lead in biotechnology, a protective approach is necessary, but not sufficient. One important contribution the government can make to the health of the biotechnology sector is to facilitate scientific exchange and endeavor. While the intellectual property of commercial entities must be protected to promote product development, basic scientific research is meant to be shared. Scientific information sharing laid the foundation for the industry with the introduction of genome sequencing and CRISPR gene-editing. Do-it-yourself laboratories are now expanding science's reach to support new, nontraditional innovators such as computer science hobbyists and high school students in making significant scientific breakthroughs. Addgene, a non-profit in Cambridge, Massachusetts serves as a repository for all new small DNA molecules known as plasmids, which are the building blocks for other discoveries. They then provide these plasmids at minimal cost to other scientists to help facilitate scientific development.<sup>97</sup> Open science encourages exponential growth in scientific discovery and allows America to retain a leading edge.

To fully exploit this potential, we need a coordinating body to help facilitate collaboration and coordinate U.S. Government policy. In the past, the Office of Science and Technology Policy in the White House took the lead on biotech initiatives, including information sharing. The office could also help to establish clearing houses or databases of information to be sure that researchers working on similar efforts are aware of one another's work (as appropriate given potential commercial concerns) and coordinate supporting education policy. Many of the most innovative approaches taking place today borrow from not only biology but also engineering, physics, chemistry, and computer science. Having personnel well-prepared to advance scientific exploration is key to the success of the industry. The U.S. Government can assist by promoting technical training through community colleges and advocating a cross-disciplinary approach on university campuses. According to a recent poll by the University of Michigan, the two majors that generated the highest return on investment were software design and chemical engineering, both of which are vitally important to biotechnology.<sup>98</sup>

## Support

Protecting and facilitating development can have a real impact, but to be a global leader in this dynamic industry, the government will need to actively support U.S. biotechnology. More public-private partnerships would support industry development and technology sharing. The government can also assist in creating bioinformatics-based tools to help speed the process of exploration, discovery, and testing. The government could also provide more non-diluted funding to support basic research, which can form the foundation of economic growth and

### FACILITATE

- Utilize the Office of Science and Technology Policy to coordinate government role in information sharing in biotech cross-discipline endeavors.
- Promote cross-disciplinary STEM education at all levels.
- Encourage an "open science" approach to developments in biotechnology to spur innovation while supporting increased awareness of threats.

*Figure 14. Policy Recommendations: Facilitate*

innovation. Another way to support the industry would be to provide tax incentives for investors in the biotechnology industry, giving investors and companies a reason to stay in the United States.

The government can also help by supporting the development of clusters which have been instrumental in allowing new industries to flourish. Local and state-level innovation centers have demonstrated that providing an ecosystem with an underlying educational foundation, supporting rules and regulations, access to technical expertise, technological innovation, and financing, are all key to a thriving industry. The government can help support these through seed funding for incubation centers, much of which could be established on a cost-recovery basis with a fee for successful firms to help recapitalize the effort. Expanding the effort by providing technical and, where possible, financial assistance overseas would expand U.S. influence and build a better industry and more stable economy.

Government can help support industry in non-financial ways as well. Some of the most significant hurdles for biotech firms are regulatory in nature. Restructuring regulatory regimes to facilitate streamlined approvals could have significant impact, such as by designating a single point of contact for new entrants into the biotech market rather than requiring that they work their way through a wicket of three different agencies to ascertain appropriate regulatory authorities governing their innovations. The government could also supply urgent need access for critical evolving technologies, particularly in the pharmaceutical realm. Another significant contribution to support the rapid adaptation of new technologies would be for the FDA to provide incentives for computer modeling (or “in silico”) in clinical trials.

Given the difficulties and expense of gaining approvals for new technologies, allowing government entities to serve as participants in trials could support promising technologies while giving the government access to new technologies at the earliest possible stages. In fields such as battlefield medicine, precision medicine, and basing support, such early testing could give the U.S. comparative military advantage while helping to spur industry growth.

As the U.S. seeks to maximize the promise of biotechnology, the government could pave the way for consumer acceptance of new technologies by conducting a public education campaign to explain the science behind them. One of the major constraints to the optimization of biotech both domestically and globally is a misunderstanding of the science involved. Greater public education could vastly enhance the ability of biotechnology to meet our domestic and national security needs. Similarly, leading efforts to establish international norms to govern development in biotechnology would serve to protect from the dangers of unbounded exploration while providing a transparent global framework in which our industry can flourish.

## SUPPORT

- Increase funding for basic research.
- Public-private partnerships to support development and information sharing.
- Incentivize investment in biotechnology.
- Support innovation clusters as the local and state levels.
- Streamline regulatory regimes and adapt to current and emerging technologies.
- Support “in silico” model to speed adaptation of new technologies.

*Figure 15. Policy Recommendations: Support*

### Cross-Cutting Recommendations

- Expand opportunities to facilitate “open science” collaboration to spark research and innovation.
- Broaden intellectual property protections.
- Ensure the CFIUS process properly protects biotech competitive advantages and personal protection through biodata.
- Promote cross-disciplinary STEM education at all levels.
- Incentivize cluster approach to innovation centers.
- Expand funding in basic research.
- Lead internationally in biotechnology norms of conduct.
- Restructure and streamline regulatory framework while ensuring it remains adapted to emerging technologies.
- Explore using the military as a test bed for biotech advances in battlefield medicine, precision medicine, and expeditionary sustainment.
- Conduct a public education campaign about biotechnology's benefits and risks associated with biodata proliferation.
- Create a Bio-defense council to facilitate streamlined interagency efforts in support of emerging technologies and identification of threats.

Figure 16. Cross-Cutting Recommendations



## Conclusion

As we consider the most pressing needs of U.S. national security, biotechnology offers a means to meet them. It gives us tools to protect and promote American interests, while also developing our economy and improving the lives of our people. But the nascent field of biotechnology must overcome many inherent challenges before reaching its potential. Except for some key pharmaceutical research, the current industry model incentivizes modest developments for more certain commercial gain, rather than supporting the full measure of transformation biotechnology could represent. As small firm innovators face the “valley of death,” it is in the U.S. national interest to help bridge that gap to allow the industry to flourish; driving economic growth and building U.S. competitive advantage.

If we hope to lead in the evolution and exploitation of biotechnology, we must acknowledge the challenges built in to the current industrial model and work to overcome them. We will need to strike the right balance with respect to regulatory hurdles, the appropriate role of government, intellectual property protections, capital markets, privacy concerns, and international norms of conduct. In all these areas, there is a pivotal role for government to play in developing the technology to our national benefit, but there are dangers in government distorting the playing field. Other rivals, notably China, have aggressive national strategies to leverage the capabilities of biotech. The choice confronting the U.S. is whether to cede that ground to China, or to invest in and support the sector to retain and increase our competitive advantage.

If we are to make the most of this tool, and retain the U.S. competitive advantage in an evolving, dynamic field, government involvement is critical. Public-private partnerships, strong intellectual property laws, transparent laws and regulatory frameworks, and evolved capital markets have been the keys to unlocking American innovation in the past. We need to draw on these assets and shape them to meet the unique needs of the biotech industry. As with the evolution of other innovative industries in the past, such as the high-tech sector, striking the right balance between initial government support and the innovative forces of the private sector could unleash the full dynamism of the biotechnology sector. Our rivals recognize the potential of

biotech. If we wish to fully realize the contributions biotechnology can make to our economy, way of life, and all aspects of national security, the U.S. needs to take decisive actions to support the industry and tap into its promise.

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## Appendix A. Recommendations

The following are consolidated policy recommendations for biotechnology as they apply to each specific pillar of the 2017 National Security Strategy.

### **PILLAR I: Protect the American People, the Homeland, and the American Way of Life**

#### *Borders, Threats, Cyber, National Resiliency*

- Create a Bio-defense Council to facilitate and streamline interagency efforts. Such a council should be led by a member of the executive branch (preferable Senate confirmed) who can leverage the resources necessary for synergy across this multi-discipline area of focus.

**Threats/cyber:**

- Conduct a Public Awareness Campaign to inform and educate regarding biodata and why it should be protected.
- Resource and expand Scientific Security Training to amplify the efforts of the FBI WMD groups that perform outreach to the scientific research community, and industry, to break down barriers and create a frontline of defense.
- Require Mandatory “[Infraguard](#)” participation by select biotechnology sector players to raise awareness within the industry of the evolving risks and threats.
- Establish a Research Data Clearinghouse to provide a friction-free, trustworthy validation portal to educate and create confidence in data access and sharing.
- Establish a Commercial Transaction Clearinghouse to increase visibility into transactions outside of the CFIUS process and to increase probability of clean transactions. Otherwise, review and elevate suspect transactions before data changes hands.
- Develop Terms of Use Labeling & Clarity Requirements to dissuade consumers from agreeing to terms without reading and understanding what they are agreeing to.
- Create an International Scientific & Commercial Clearinghouse to create a larger community that further streamlines data access and transfer, as well as codify norms and standards.

**Genetic diversity in agriculture**

- Centralize government leadership – FA genetic diversity goals.
- Expand the germplasm enhancement of Maize (GEM) project model.
- Incentivize private research & development in crop diversity.
- Incentivize pro-vigor animal husbandry methods.
- Develop a FDA & USDA regulatory fast-lane for genetic diversity.
- Modify the Farm Bill to subsidize genetic diversity.

**Resilience:**

- Increase public funds for basic research.
- Increase incentives (e.g., tax credits) for companies to become involved in agricultural biotechnology.
- Streamline and update regulatory frameworks to ensure they are adapted to technology utilized in the commercial sector.

**PILLAR II: Promote American Prosperity**

*Economy, Relationship, Lead Research/Innovation, Promote and Protect Security Innovation Base, Energy Dominance*

**Economy, lead research/innovation, promote security base:**

- Restrict use of gene drives through patents.
- Restore the Office of Technology Assessment (OTA) to ensure Congress makes sound decisions in this area.
- Fund the OTA to provide our lawmakers the technical knowledge they need to make informed decisions regarding emerging technologies to include gene editing.

**Free, fair, reciprocal relationships, lead research/innovation, promote and protect security innovation base:**

- Encourage international expansion and emphasis of private organizations such as [BIO](#).
- Encourage and support international relationships amongst community labs (sister labs).
- Encourage participation in international conferences and challenges related to biotech and possibly creatively assist with funding.
- Expand publically available resources to counter IP infringement.
- Continue emphasis on actions and measurements of effectiveness of the Joint Strategic Plan on IP enforcement.

**Lead in Research and Innovation, Promote Security Innovation Base:**

- Strengthen the U.S. industrial base in the sector by providing incentives for companies to discover, develop, and implement technologies in the U.S.
- Consider reopening the Trans-Pacific Partnership (TPP).
- Ensure strict, disciplined adherence to the CFIUS process ensuring the competitive advantage is maintained.
- Maintain the global competitive advantage in biotechnology by aggressively addressing unregulated and undocumented Chinese advancements in the industry.
- Create a federal economic development fund fostering incubator biotechnology clusters associated with life science academia.
- Increase non-diluted federal funding for national security projects for commercial companies through expansion of DARPA or creation of other similar agencies sourcing commercialization of dual use products.
- Provide federal tax benefits for angel investors for start-up biotechnology companies.
- Restructure CFIUS process, adding legislation allowing Congress to review acquisition of minority stakes in U.S. companies by foreign investors.

**Lead, promote, protect innovation:**

- Balance any new laws, regulations, or policy to protect biodata that would impinge on economic activity in the near-term with the need for a long-term innovative economic engine.

**Lead, promote, and protect innovation: Economic Advantage:**

- Establish a Biotech Enhancement Team (BET) for monitoring the Biotech industry and encouraging the most promising firms to cooperate with the DoD.

- Provide roadmaps to train people and provide a continuous stream of employees who know Biotech.

### **Energy Dominance**

- Include algae in the Farm Bill as a crop to provide some insurance to algae farmers for losses on par with regular crop farmers.
- Include algae in the Renewable Fuel Standards (RFS) cellulosic umbrella for minimal volume requirements for fuel blends.
- Increase the amount of R&D funding to Federally Funded Research and Development Centers or consolidate a lead organization to further the algae pathway.
- Reestablish the National Alliance for Advanced Biofuel and Bioproducts (NAABB), which ended in 2013 just after CRISPR was found to be a reliable gene editing tool, to address the engineering challenges to potential good algae strains for lipid production.
- Include alternative and renewable fuels as part of the National Security Strategy.

## **PILLAR III: National Security: Peace through Strength**

### *Competitive Advantages, Military Capabilities, Diplomacy*

- Establish a genetic privacy policy commiserate with the 2008 Genetic Information Nondiscrimination Law.
- Add genetics as a protected category for Equal Opportunity (EO) - tailor to already current EO Air Force regulation.
- Establish a Precision Medicine (PM) Center for Excellence to transition basic research into applied research.
- Recruit service members on a volunteer basis initially, establish a strong foundation for informed consent to PM, and train staff involved on how to obtain informed consent.
- Establish a policy on how to communicate findings to individuals, to include incidental findings.
- De-identify genetic data in the electronic health record not already in use until privacy policy is established. Use the sensitive information option in the electronic medical record and track access to the module and restrict for need to know only. Do not include information in medical decision making and mainstream prior to establishing a solid privacy policy and applicable informed consent pathways.
- Establish studies to look at the role of genomic data and musculoskeletal injuries to tailor preventative guidelines, physical training and treatment to decrease the burden of musculoskeletal injuries on readiness.
- Use precision medicine as a force multiplier and not as an eliminator- – leverage science to improve performance and to transition teenage citizens into warrior athletes.
- Recruit and retain genetic counselors, provide a competitive compensation package.

- Implement precision medicine education, genetic counseling for medical students, nurse practitioners, and physician assistants at the Uniformed Service University and its affiliates.

#### **Military capability:**

- Use the Orphan Drug and Humanitarian Use Device regulatory processes to incentivize companies to produce battlefield specific devices.
- Seek a new regulatory pathway specifically for battlefield products with the Limited Population Antibacterial Drug pathway as a model.
- Apply military-developed solutions to reduce waste, produce fuel, water or food, to megacities, to benefit the U.S. economy by using fewer resources and saving more money for alternatives, particularly in times of national disaster.

#### **Competitive Advantage:**

- Replicate a military operating base in an austere environment in the U.S. for research institutes and industry to conduct trials and research and incentivize participation.
- Apply promising results out of programs like the Armies Net Zero to austere forward military operating bases; combine with results of the civil sustainable city efforts.

## **PILLAR IV: Advance America's Influence**

### *Aspiring partner, Multilateral fora, American values*

#### **Multilateral fora, American values:**

- Join the United Nations Biological Diversity Convention.
- Establish an international framework for gene drive research and application.
- Develop international regulatory compatibility and acceptance of gene edited products.

#### **Aspiring partners:**

- Ensure the Department of State's Office of Agricultural Policy is adequately resourced, so it can continue its work of facilitating market access for U.S. agricultural products .
- Increase funding for public education to set conditions for future success.

#### **Multilateral Fora, Champion American Values**

- Rejoin UNESCO as a partial member, only on the science side.
- Work for: passage of the moratorium on genome engineering of the human germline; an international binding ban on human cloning for reproductive purposes; a global standard for engineering the human genome; as well as national legislation and international regulations regarding modifying the human genome and producing/destroying human embryos.

- Build the capacity of national regulators in other nations and expand the approach of the Codex Alimentarius, the internationally recognized food standards protocol, to pharmaceutical and environmental science regulation. Fund training and standardization efforts with a fee for U.S. patent filers who indicate plans to sell their products in countries where we provide regulatory assistance.
- Offer protection of indigenous biodiversity as an asset, if not entirely protected IP.
- Increase the U.S. focus on science diplomacy as a recognized professional career path within the Foreign Service.
- Expand science fellows program.
- Seek additional Science and Technology Agreements.
- Reconstitute the Office of Science and Technology Policy at the White House or empower the State Department to coordinate all overseas initiatives. Establish a database of efforts.
- Create an internet platform to publicize opportunities and ongoing efforts to encourage collaboration.
- Build an international scientific body to seek entrepreneurs to develop solutions to global problems, i.e. climate change.

### **Cross Cutting Recommendations**

- Find more opportunities to facilitate “democratization of science/open science” to support research and innovation.
- Establish clearing house/databases.
- Broaden IP protections to incentivize discovery.
- Ensure protection of U.S. biotech assets including biodata, companies, and infrastructure (CIFIOUS).
- Promote cross-disciplinary scientific education.
- Provide more non-diluted funding.
- Expand cluster approach to innovation centers.
- Reestablish coordinating body.
- Assure access to markets for start-ups (i.e. algae in biofuels, agriculture products).
- Lead internationally in establishing norms in Biotech.
- Restructure regulatory regime to facilitate streamlined approvals (i.e. single POC for 3 agencies) and urgent need access.
- Consider utilizing the military as a testing ground for relevant new technologies (battlefield medicine, precision medicine, basing support) to give the U.S. comparative military advantage while helping to spur industry growth.

- Conduct Public Education Campaign.

## Appendix B. Definitions

**\*Bioeconomy:** The bioeconomy comprises those parts of the economy that use renewable biological resources from land and sea – such as crops, forests, fish, animals and micro-organisms – to produce food, materials and energy.

**\*\*Biomarker:** a measurable substance in an organism whose presence is indicative of some phenomenon such as disease, infection, or environmental exposure.

**\*\*\*Chromosome:** The self-replicating genetic structure of cells, containing genes, which determines inheritance of traits. Chemically, each chromosome is composed of proteins and a long molecule of DNA

**\*\*DNA:** Deoxyribonucleic acid, long chain of molecules in most cells that carries the genetic message

**\*\*Epigenome:** All the chemical compounds that tell the genome what to do

**\*\*Exposome:** the measure of all the exposures of an individual in a lifetime and how those exposures relate to health

**\*\*\*Gene:** The fundamental physical and functional unit of heredity. A gene is typically a specific segment of a chromosome and encodes a specific functional product (such as a protein or RNA molecule).

**\*\*\*Gene expression:** The result of the activity of a gene or genes which influence the biochemistry and physiology of an organism and may change its outward appearance.

**\*\*\*Gene (DNA) sequencing:** Determining the exact sequence of nucleotide bases in a strand of DNA to better understand the behavior of a gene.

\*\*\***Genetic engineering:** Manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.

\*\*\***Genetically engineered organism (GEO):** An organism produced through genetic engineering.

\*\*\***Genetic modification:** The production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods. Some countries other than the United States use this term to refer specifically to genetic engineering.

\*\*\***Genetically modified organism (GMO):** An organism produced through genetic modification.

\*\*\***Genome:** All the genetic material in all the chromosomes of a particular organism

\*\*\***Genomics:** The mapping and sequencing of genetic material in the DNA of a particular organism, as well as the use of that information to better understand what genes do, how they are controlled, how they work together, and what their physical locations are on the chromosome.

\*\*\***Genotype:** The genetic identity of an individual. Genotype often is evident by outward characteristics but may also be reflected in more subtle biochemical ways not visually evident.

\*\***Omics:** All biology disciplines ending in omics such as proteomics, genomics, etc.

\*\***Microbiome:** the microorganisms in a particular environment (including the body or a part of the body).

\*\*\***Molecular biology:** The study of the structure and function of proteins and nucleic acids in biological systems.

\*\***Nutrigenomics:** Interaction of diet and genes

\*\***Penetrance:** The proportion of individuals carrying a particular variant of a gene (allele or genotype) that also expresses an associated trait (phenotype).

\*\*\***Phenotype:** The visible and/or measurable characteristics of an organism (how it appears outwardly).

\*\***Proteome:** the entire complement of proteins that is or can be expressed by a cell, tissue, or organism

\* **Denotes the following source:** <https://ec.europa.eu/research/bioeconomy/index.cfm>

\*\* **Denotes the following source:** Online biology dictionary- <https://biologydictionary.net/>

\*\*\* **Denotes the following source:** <https://www.bio.org/articles/glossary-agricultural-biotechnology-terms>

