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Industry Study

Final Report
Biotechnology Industry

The Industrial College of the Armed Forces
National Defense University
Fort McNair, Washington, D.C. 20319-5062

BIOTECHNOLOGY 2010

ABSTRACT: The United States (U.S.) is the global leader in the biotechnology industry delivering tremendous national security and economic benefits. This strategic industry can potentially provide innovative and revolutionary solutions to emerging and enduring challenges such as foreign oil dependence, incurable diseases, global food and water scarcity, and the defense of our homeland. That potential underscores the strategic imperative for the US to maintain its leadership and sustain its competitive advantage in this industry. To maintain U.S. dominance and competitive advantage, the nation's leadership must take proactive measures to address growing international competition and challenging global economic conditions. Specific measures include providing robust public funding and private sector investment incentives, promoting a more effective and agile regulatory framework, developing and maintaining human capital talent, improving public awareness and engagement, and supporting innovation.

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PLACES VISITED

Domestic:

Abbott Laboratories, Abbott Park, IL
Arcadia Biosciences, Davis, CA
Astellas Pharma US, Deerfield, IL
Bay Bio, San Francisco, CA
Biotechnology Industry Organization, Washington D.C.
Bio-Rad, Hercules, CA
Broad Institute, Cambridge, MA
Burrill & Company, San Francisco, CA
Charles River Laboratories, Wilmington, MA
Codexis, Redwood City, CA
Genentech, San Francisco, CA
Genzyme, Cambridge, MA
Harvard Stem Cell Institute, Cambridge, MA
Hollister, Libertyville, IL
QB3, San Francisco, CA
SRI International, Menlo Park, CA
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University of Maryland at Baltimore, Baltimore, MD
US Army Medical Research Institute for Infectious Diseases, Fort Detrick, MD
US Department of Agriculture, Agricultural Research Service, Beltsville, MD
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International:

Abbott Laboratories, Singapore
Academia Sinica, Taiwan
Agency for Science, Technology & Research, Singapore
American Institute in Taiwan, Taiwan
Biotechnology Office, Science & Technology Advisory Group, Taiwan
Council of Agriculture Affairs, Taiwan
DSO Defense Medical & Research Institute, Singapore
Global Emerging Technology Institute, Japan
Industrial Technology Research Institute, Taiwan
Institute for Biotechnology & Medicine Industry, Taiwan
Jurong Town Corporation, Singapore
Malaysian Biotechnology Corporation, Malaysia
Malaysian Genomics Resource Center, Malaysia
Nankang Biotechnology Incubation Center, Taiwan
National Institute of Advanced Industrial Science & Technology, Japan
Sime Darby Technology Center, Malaysia
Taiwan Food & Drug Administration, Taiwan
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INTRODUCTION

"If you want to change the world in some big way, that's where you should start – biological molecules."[1] *- Bill Gates, Chairman, Microsoft Corporation*

Biotechnology has the potential to solve some of the most complex problems of the 21st century. As an industry, biotechnology is unparalleled in its potential to impact global health, food and water security, energy security, and the environment. This innovation-based industry is strategically significant because it impacts both national security and the sustained growth of the domestic economy. For the United States to maintain its current competitive advantage in the industry, it must focus on policy and investments which strengthen the industry's ability to rapidly innovate and to transform innovative ideas into products and services for the global market.

The purpose of this report is to conduct a strategic-level examination of the biotechnology industry – an industry vital to the nation's security and economic welfare. The study includes over fifty activities spanning lectures by leading biotechnology experts and field visits to important government and corporate organizations. The industry study program includes travel to key domestic and international biotechnology centers such as Boston, Chicago, San Francisco, Taiwan, Singapore, Malaysia and Japan. The study methodology uses critical thinking to analyze the structure, conduct and performance of the biotechnology industry and market sectors. This includes using the five forces of competition (new entrants, supplier power, buyer power, substitutes and the degree of rivalry) to assess the capacity and capability of U.S. biotechnology firms to deliver globally competitive products and services. Additionally, the methodology evaluates the biotechnology industry's performance in meeting national security interests and promoting economic growth.

The report is separated into four primary sections. The first section examines the current condition of the biotechnology industry with an assessment of the overall health, structure, conduct and performance of the industry. This section is followed by an analysis of the most serious challenges facing the industry in the U.S. It studies both the domestic and foreign nature of the industry and how the dynamics affect competition. The third section provides both a short-term and long-term outlook for the U.S. biotechnology industry. Finally, the last section reviews the government's role and provides recommendations on government support to the U.S. biotechnology industry. Three essays are also included highlighting some of the major issues confronting the biotechnology industry.

THE INDUSTRY DEFINED

Biotechnology is the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge and biotechnology products and services.[2]

Biotechnology Sectors

Healthcare	Agriculture
• Pharmaceuticals • Vaccines • Protein Therapeutics • Diagnostics • Devices	• Genetically Modified Plants & Animals • Improved yields • Nutrition • Vaccines & therapeutics
Industry & Environment	**Biodefense**
• Micro-organisms • Engineered enzymes • Renewable carbon sources • Biofuels & Bioplastics • Remediation	• Prevention & Protection • Detection & Diagnosis • Therapy & Remediation

Biotechnology creates new products and processes across a broad range of industries. This is evident in the four distinct biotechnology market sectors: healthcare, agriculture, industrial and environmental, and biodefense as noted in Figure 1. The human healthcare segment dominates the biotechnology industry accounting for over 62% of the current market.[3] This sector includes a wide variety of products and services to include medical, diagnostics, and therapeutic drugs and vaccines. Since the early 1980's, biotechnology has played a growing role in the healthcare industry targeting improved public health, well-being, and productivity.

The agriculture sector focuses on developing new varieties of food, feed, and fiber crops that are genetically modified (GM). The genetic changes impart beneficial traits such as improved nutrition and drought resistance. The U.S. is the agricultural biotechnology leader in quickly adopting GM technology and creating new food crop markets domestically and in other parts of the world. Agricultural biotechnology provides value for farmers, consumers, and the environment by increasing crop and livestock yields, delivering healthy sources of reliable food to consumers, and decreasing the environmental impacts of herbicides and pesticides. This sector is also pursuing new sources of biomass such as GM corn, soybeans, algae and switch grass that can be more easily converted into biofuels by the industrial sector.

Industrial biotechnology is a broad sector that employs provides solutions to some of the world's most pressing energy and environmental concerns by developing new fuel sources, enabling cleaner processes, improving chemicals and detergents, producing less waste, and using less energy and water. Some of its major applications include bioenergy, bioprocessing, and environmental bioremediation. An example of environmental bioremediation is the use GM organisms to remove difficult-to-degrade materials for water treatment and pollution control.[4]

Biodefense has the potential to make substantial contributions to national security and support global U.S. economic competitiveness. Potential areas include: infectious disease detection, prevention and treatment; biomaterials for defense applications; biosecurity; and biosurveillance. Defense specific areas include improved warfighting capabilities, combat lifesaving, sensors, armor, and explosives.

CURRENT CONDITION

The assessment of the current condition of the industry included evaluating the biotechnology industry's structure, conduct, performance, business strategies and level of competition. Each element of the assessment reveals the strategic benefit the industry holds for the nation.

Industry Structure

The industry structure for biotechnology is shaped by three factors: market competition, market concentration, and the roles of the stakeholders. Competition within the biotechnology industry exhibits monopolistic characteristics for three primary reasons. First, the products and services are not homogeneous and can be differentiated by characteristics other than price. Second, firms are free to enter and exit the market. Small to medium-sized enterprises dominate the biotechnology industry with the majority of these innovative firms focused on research and development (R&D). Market growth and first-to-market benefits in the form of patents and

licensing will continue to encourage new entrants to the industry. On the other hand, large requirements for capital and a high degree of government regulation restrict entry. As a result, barriers to entry are at a medium level.[5] Finally, the intellectual property (IP) regulations allow firms some control in setting prices in the market to recoup investment costs.

Market concentration measures the influence of the largest companies in an industry. Within the biotechnology industry, the top four industry players account for only 37% of industry revenue, and therefore market concentration is considered low. The major industry players are Amgen, Genentech, Syngenta and Monsanto.[6] These four companies are split between healthcare and agriculture, the two largest biotechnology industry sectors. Nearly 90% of the enterprises are small to medium sized companies with less than 500 employees.[7]

The stakeholders are the final factor shaping the industry structure. There are six primary stakeholders within the biotechnology industry. They are the investment community and venture capitalists, academia, small and medium-sized businesses, large businesses, consumers and the government. The role of the investment and venture capitalist community is to fund product research, development, approval, manufacture and distribution. The next stakeholder is academia, whose role is to educate the workforce in the science, technology, engineering and math (STEM) fields. Additionally, academia-conducted basic research often results in the creation of small spin-off firms to perform the applied research and product development. Small and medium-sized businesses are the next stakeholder group. This group serves as the innovation engine for the industry. They also perform activities across the product lifecycle, such as conducting research, development, manufacturing and distribution of biotechnology products and services. Large businesses often perform a similar role to small and medium-sized businesses. Since they tend to be risk adverse, large firms focus primarily on acquiring promising new technologies and optimizing the manufacturing and distribution processes. Consumers create demand for the industry across all sectors. The government is the final stakeholder and will be addressed later in the report.

Industry Conduct

Industry conduct for biotechnology is affected by four primary factors. The first factor is the large capital requirement**.** The average cost to bring a product to market across several biotechnology sectors is approximately $1 billion. More than half of this cost is associated with financing for the extended period of product development from discovery, through clinical trials and finally government approval. Additionally, for biopharmaceuticals, 40% of the expenditure per successful drug actually covers the cost of the firm's failed projects.[8]

The second factor affecting industry conduct is the level of R&D required. The average time to successfully bring a biopharmaceutical product to market is over 10 years with the majority of this time devoted to R&D activities. Despite providing over $108 billion in government funding, private investment still accounts for 70% of industry R&D spending.[9]

The third factor is hiring and retaining accomplished scientists and bioengineers. This provides the human capital essential for success and influences the amount and duration of capital financing by venture capitalists. One solution within industry has been the formation of biotechnology clusters centered near major U.S. cities such as Boston and San Francisco, with proximity to academia, skilled labor, technology infrastructure, a good quality of life and strong government support. These bioclusters are perceived by other nations as a key contributor to U.S. innovation and dominance of the biotechnology industry.

The final factor affecting industry conduct is pricing. The overall effect of the factors above is to raise the cost of biotechnology products. As a result, a biologic therapy is often priced higher than a comparable chemical therapy. This pricing scheme is similar across several industry sectors as patent protection allows monopolistic pricing for pest-resistant seeds, enzyme cleaning agents and biopharmaceutical drugs. Because of the value to their customers, biotechnology companies are able to price their products to recoup costs and make a profit prior to patent expiration. This is a key reason for the successful of the U.S. biotechnology industry.

Industry Performance

Overall, the industry has continued double-digit revenue growth achieving 10.3% during the period 2005 to 2009. Total revenue, revenue growth rates and employment have also experienced sustainable growth as noted in Figures 2. – 4. below.[10]

Revenue

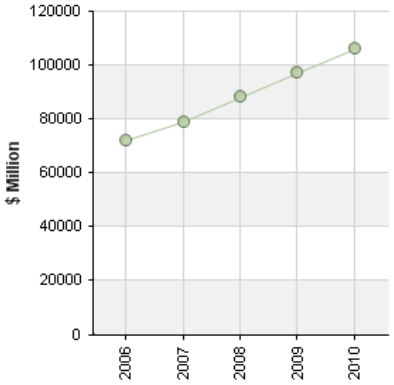

Figure 2.

Revenue Growth Rate

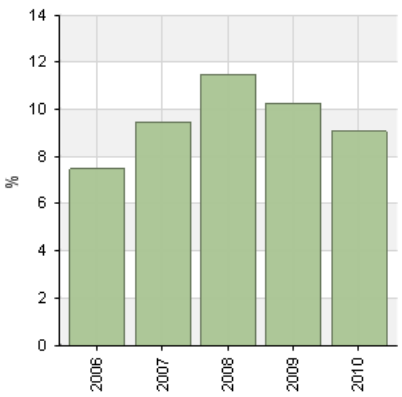

Figure 3.

Employment

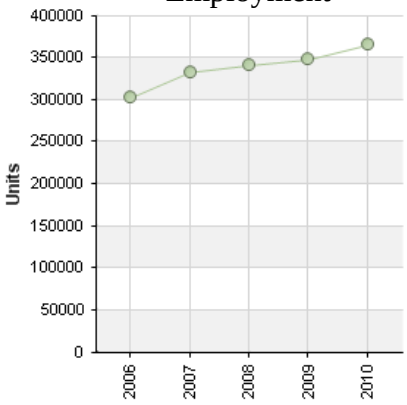

Figure 4.

There are several drivers for this sustained growth in the U.S. biotechnology market. The first driver is the aging population and increased life expectancy.[11] With an increasing age demographic, the U.S. will see increased demand for medical therapies focused on an older population, specifically addressing cancer, arthritis, diabetes, Alzheimer's, and heart disease.

A second demand driver is an increasing global demand for food, water and energy. The U.S. recognizes that biotechnology can provide solutions to addressing these needs and is allocating resources to meet this demand. Other nations are allocating significant government funds to build the required infrastructure and develop these capabilities as well.

The final demand driver for continued growth in the U.S. biotechnology industry requires a growing public acceptance of the benefits and potential of biotechnology.[12] Most published information emphasizes the benefits of biotechnology such as developing innovative medical solutions, increasing the yields and nutritional value of crops, discovering alternative energy sources, and improving the nation's overall quality of life. Strong societal support is required if the U.S. is to remain the global biotechnology leader.

Industry Strategies

Biotechnology industry firms implement a variety of strategies based on their size, capital resources and core competencies. The typical strategy for a biotechnology firm is to conduct R&D, create a product or process, secure financing, build the infrastructure, hire employees to commercialize the product or process, and scale the firm as demand increases. The ultimate goal is to move up the industry value chain, become a publicly-traded company or get acquired by a larger firm. Other common industry strategies included licensing IP, forming alliances and partnerships with large businesses, and developing products and processes that directly support other firms in the industry. For example, the seminar visited Charles River Laboratories, a direct support firm providing customers with a variety of animal models for clinical activities.

Entrepreneurship is an important strategy of this industry and has been since Genentech was formed by a venture capitalist and biochemist in 1976. Today, this strategy continues to be a growth engine for biotechnology firms determined to make that next big discovery and a catalyst for innovation in the industry. Most entrepreneurs concentrate on the R&D market often led by academia. Universities grant these entrepreneurs access to their laboratories in exchange for a share of rights to the discoveries. Government grants or contracts are the primary funding source for these research activities with the plan to rely on licensing, partnerships and alliances to generate future streams on revenue.

Although the financial crisis and tight credit conditions are causing firms to be more conservative, biotechnology firms are adapting. The rate of mergers and acquisitions increased over the past two years. The most notable was with the acquisition of Genentech by Roche in 2009. Firms of all sizes are employing research candidate optimization strategies to conserve cash and limit investments on only the most promising projects. While smaller firms are retrenching by focusing on specific aspects of the industry lifecycle, for instance, specializing in supporting the clinical trial process or late stage development, larger firms are trying to reduce capital investment by outsourcing activities that can be done more cheaply overseas.

Foreign Competition

The U.S. leads the global biotechnology industry with nearly 43% of market revenue.[13] Both Europe and Asia each account for 21% of the global market.[14] The U.S. consistently yields a trade surplus, exporting more than it imports. This trade surplus continues to grow at a faster pace than both Europe and Asia.[15] Several factors affect foreign competition to include: government taxes, incentives and support; patent and intellectual property protection; human capital and education; and market pricing. All of these factors need to be effectively addressed to attract the private investment necessary to allow firms to recoup their investment costs and increase profitability. Based upon these factors, the risk of foreign competition is considered medium for the U.S. biotechnology industry.[16]

To better promote their biotechnology industries, countries in Europe and Asia are adopting the U.S. regional biocluster model that effectively teams government, academia, and private industry. This biocluster model, also known as the “triple helix”, has been used successfully in San Francisco and Boston. One notable difference between the U.S. and other countries is the source of funding. U.S. bioclusters are funded primarily by private investment while European and Asian bioclusters are funded by direct government investment.[17] Only time will tell if the government-funded model will create the same innovative synergy as the U.S. biocluster model.

As observed during international travel, a number of Asian countries are making the investments today to lay the foundation to build a more vibrant biotechnology industry in the future. Taiwan has identified biotechnology as one of the nation's six priorities and developed the Diamond Action Plan to methodically plan, prepare and implement their biotechnology industry using a deliberate, time-phased approach.[18] The Malaysian government has determined biotechnology to be one of the key strategic industries for growing the Malaysian economy. It is in the process of implementing the Nine Thrusts of the National Biotechnology Policy to create the framework needed for long-term growth.[19] Japan lags behind the U.S. in the biotechnology industry, but is making considerable efforts and investments to become globally competitive.

Perhaps the best example of creating the ideal conditions for a globally competitive biotechnology industry is Singapore. The Singapore government has developed a comprehensive strategy which invested over $700 million to develop the biotechnology infrastructure, provide industry seed funding, attract international scientific talent, and establish a wide range of pro-industry policies and regulatory framework to promote and grow their biotechnology industry. Singapore has also signed Free Trade Agreements (FTA) with the U.S. and other key countries to increase bilateral trade and draw private investors.[20] To attract foreign companies and investors, Singapore pushed through pro-biotechnology tax laws including a low corporate tax and a 10-year tax exemption for strategic research.[21] The results speak for themselves. The Singapore biomedical sciences industry is growing 33% annually to reach $9.4 billion in sales.[22]

CHALLENGES

The most significant challenges facing the biotechnology industry include private investment, public funding and policy, IP protection, regulatory framework, human capital, and public acceptance. These challenges also represent the current strengths of the U.S. biotechnology industry. The U.S. government and biotechnology industry must recognize the challenges and take the necessary steps to sustain the nation's global leadership position.

Private Investment

The recent financial crisis has affected private investment in the biotechnology industry, and tightening credit markets have made it much more difficult for companies to secure funding. Additionally, the decline in venture capital funding and Initial Public Offering (IPO) financing has led to severe cash shortages for all but the largest biotechnology companies. The recent economic crisis has been especially devastating to small and medium-size biotechnology firms, impacting their ability to raise the venture capital necessary to develop science beyond proof-of-concept into commercially viable goods and services. Biotechnology firms rely on massive initial capital investment before they can bring new products to market. Many of these companies are startups, born in academic research labs or incubators, whose creators must conduct extensive R&D efforts, raise the capital required to prove out and scale the technology, build a team with the right skills – technical, entrepreneurial, and the appropriate industry experience in order to succeed. As a result of the economic downturn, private equity and venture capital markets have proven insufficient to finance promising, early-stage scientific research beyond the basic research stage and into commercial viability. This critical phase of investment is often referred to as the "valley of death" within the biotechnology industry, given the likelihood for firms to fail in the early concept stage due to insufficient funding.

According to recent studies, the current economic environment has resulted in investors redirecting capital away from biotechnology.[23] This has driven firms to pursue new avenues to secure needed cash and ensure survival. Given the enormous technical and financial challenges which characterize the biotechnology industry, a firm's ability to conduct the necessary R&D and garner funding can spell the difference between success and failure. Partnerships, mergers and early-stage buyouts have now become critical decision points in a firm's life-cycle within the industry, and more often than not, represent a company's only realistic chance at survival.

Public Funding and Policy

The U.S. continues to remain a global leader in the biotechnology field in large part due to significant public funding of basic and applied research. Despite sizeable commitments of new federal dollars dedicated to grant or loan guarantee programs by Congress, investments in biotechnology companies as a whole have seen a decrease since 2009. Ensuring that firms are able to advance their goods and services through the "valley of death" has never been more important as the U.S. struggles to stimulate its economic recovery, create new jobs, decrease its dependence on fossil fuels, and develop promising biotechnology treatments and therapies. Public funding and incentive driven policy such as preferential tax treatment is essential to support the smaller, more innovative, cash-strapped companies within the industry, and to provide the resources to academia and industry to solve extremely complex problems.

Intellectual Property Protection

Intellectual property (IP) protection includes patents, trademarks, copyrights, trade secrets and exclusivity of use. The biotechnology industry is reliant upon the protection of IP for its very survival. IP protection "is necessary to secure competitive advantage and ultimately promote innovation."[24] Strong IP protection is essential to protecting proprietary information and attracting private investment for biotechnology firms. Both are needed to successfully bring biotechnology goods and services to commercial realization and allow firms to recoup investments and remain profitable.

The 1980 Supreme Court decision, *Diamond v. Chakrabarty*, established the patentability of genetically modified organisms created by man.[25] However, in a recent 2010 U.S. District Court case by a patient against a biotechnology company, the court limited the *Chakrabarty* holding, when it invalidated seven gene process claim patents because they were products of nature and not subject to patent.[26] While the case remains on appeal, it highlights the unsettled nature of patent law regarding biotechnology processes, particularly the patentability of gene sequences. Such uncertainty threatens the intellectual property of biotechnology companies and drives away potential investors.

Regulatory Framework

The biotechnology industry is highly regulated. The challenge for government policy makers at home and abroad is how to protect public interests without strangling industry innovation. Policy, regulation and law can speed innovation and the benefits it brings, or it can slow the industry to ensure safety. This balance is further complicated by many external factors including: moral, cultural and ethical questions about creating new forms of life; the implications

of ownership of biological processes; concerns about who benefits from biotechnology innovations; and political and governmental structure.

The U.S. has followed a more traditional "preventative" policy approach to the biotechnology industry that is product-focused working vertically in the distinct sectors of the industry.[27] This results in multiple government agencies at many levels having regulatory and funding authority over specific biotechnology products. While this system can promote innovation, it also can create regulatory gaps and inconsistencies that may expose society to potential risks and inefficiencies. In an industry where the technologies have applications in overlapping sectors, this has created regulatory confusion and challenges for the industry. For example, the introduction of biologically modified corn was subject to multiple regulations of the Department of Agriculture, Environmental Protection Agency, and Food and Drug Administration.[28] This overlap of agency authority often inhibits advances in the biotechnology industry.[29] In contrast, countries in the European Union (EU) and Asia have primarily taken a "precautionary" approach which is process-focused and applies horizontally across all biotechnology industry sectors.[30] While this approach regulates safety across the entire industry, it often has a stifling effect on innovation. Each policy approach has advantages and disadvantages. The challenge for all countries is to develop a framework that fosters innovation with sufficient checks and balances to prevent serious and possibly irreversible harm to the public.[31]

Regulatory systems can impose significant constraints on the development of innovative biotechnology products due to the expensive, lengthy, and complex requirements needed to bring a product to market. An enormous cost is incurred as biotechnology companies seek product approval from the many agencies having a role in the process. Biotechnology firms, particularly small companies, struggle to remain compliant with ever increasing regulation.[32] Additionally, regulatory inefficiencies increase the cost and delay the development and commercialization of new biotechnology products.[33] Biotechnology industry requires a regulatory climate that encourages and supports growth and development. The current regulatory system often struggles to deal with innovative, emerging, disruptive technologies that are not well understood or contemplated in the initial regulatory scheme.

Human Capital

The high levels of education and investment in human capital in the U.S. have been important contributors to its continued dominance in the biotechnology industry. That advantage is beginning to wane due in large part to the decreasing enrollment of American students in science, technology, engineering, and math (STEM) programs. Despite the biotechnology industry's support of domestic educational institutions to increase the production of students with the requisite skills and training to meet industry needs, there has been a continual shortfall in these fields, requiring firms to look abroad to fill vital positions. These trends will be further explored in an essay on human capital and education later in this report.

Public Acceptance

Ethical views and public acceptance can play an important role in the ability to commercialize goods or services in the biotechnology industry. One of the key public policy challenges facing the biotechnology industry is creating an active and sustained dialogue among

the government, the pubic and industry. Biotechnology holds great promise, but its innovations have the potential to change many sectors of the economy, from agriculture to energy. As scientist announce the creation of the first synthetic bacterial genome, the public struggles to understand the implications of this emerging science.[34] Unless biotechnology's innovation can overcome negative perceptions and social barriers, its full potential will not be realized. Due to the revolutionary nature of biotechnology and the associated unknowns, it is critical that the public become well educated on the benefits and risks involved in order to make informed decisions.

OUTLOOK

Short-term Outlook

Optimism currently runs strong in the biotechnology industry, but the market is clearly beginning a transition. While there are differences of opinion, the consensus is the industry will continue to grow and outperform the general market, but the rate of growth will slow, as highlighted in Figures 6. and 7.[35]

Revenue

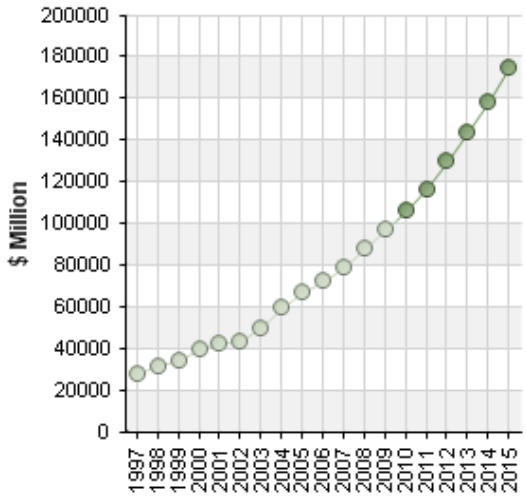

Figure 6.

Revenue Growth Rate

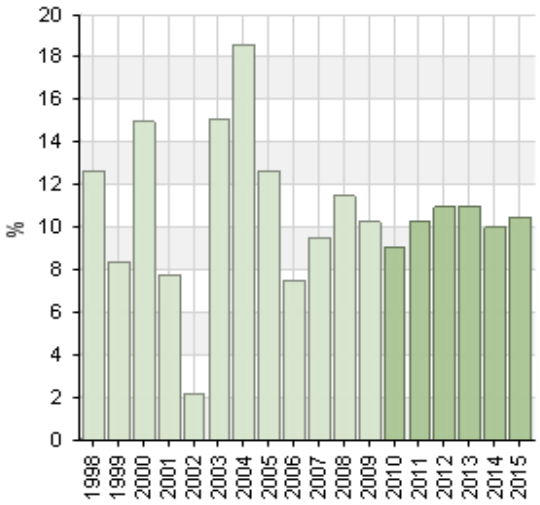

Figure 7.

There are four major trends from which future threats and opportunities will evolve. The first trend is limited access to funding. For smaller companies, this includes both access to venture financing as well as debt financing. The biotechnology sector overall saw a 19% drop in venture financing during the period from 2007 to 2008.[36] Currently, most smaller biotechnology companies have little hope to qualify for debt financing in the credit market. When combined with their traditional high capital burn rates, this means smaller firms are running low on operating capital. In the short-term, this forces partnerships between the smaller firms and larger biotechnology or pharmaceutical firms. The result fosters an environment favorable for mergers and acquisitions.[37] As the smaller firms have historically yielded the majority of industry's innovation, the lack of capital threatens to stifle future innovation.

The second trend is the maturation of the market and the resulting slower growth.[38] Firms are looking at improving efficiency and their margins by moving to more horizontal integration. The prototype biotechnology company evolved from a scientist who discovered a marketable product and then formed a company to develop and market the product. Firms are now realizing that effectively executing the range of tasks between discovery and commercialization calls for a larger talent pool than most small companies can afford. As a result, firms are focusing on leveraging their core strengths. For example, many now focus on developing IP, which they then license or sell to big pharmaceutical companies to develop into a product. This trend away from a vertical structure is positive and should strengthen the nation's competitive advantage in the face of increasing global competition.

The third trend is the growth of the global market. In 2013, the global biotechnology market is forecast to grow by 41.3% to a value of $305.7 billion.[39] This growth presents both opportunities and challenges. Clearly, larger markets offer the opportunity to expand. However, Amgen's 2010 corporate outlook indicated one of the challenges is increased future competition in the market from European biosimilars.[40] Additionally, U.S. firms have been reluctant to enter regions of the global market due to lax IP enforcement. While World Trade Organization (WTO) regulations are slowly changing behavior for the better, its compulsory licensing clause gives governments an option to break patents in a national emergency.[41] As the percentage of overseas markets increase in a firm's portfolios, so does the risk of losing a patent. This risk-to-return potentially adds more limits on a firm's access to investment capital.

The final trend is increasing competition for bio-talent, particularly in the medical and industrial biotechnology sectors.[42] Many chemical companies are already realizing a competitive edge from their investments in industrial biotechnologies.[43] Biofuels support two of the current administration's policy initiatives, to reduce dependency on foreign oil and to reduce carbon emissions, making it reasonable to expect government driven growth in the entire sector. Industry leaders are already having difficulty recruiting bioscientists and are developing programs to counter the relative attractiveness of the pharmaceutical sector.[44]

Long-term Outlook

The long-term outlook for the U.S biotechnology industry is equally positive. Envisioning a future out to 2030, three trends will significantly affect the global biotechnology industry: the aging population; population growth around the world impacting the availability of energy, water and food; and increasing global competition. To address these trends, both the U.S. and global biotechnology industries are pursuing innovative solutions that will drive market growth over the next 20 years.

As new biotechnology therapies are developed, the industry will need to address the demand for lower priced medicines and healthcare. The recently passed U.S. healthcare reform bill and the President's goal of providing affordable universal healthcare threaten the viability of the current pharmaceutical development model.[45] With an aging population, the government will need to balance policies to regulate prices while implementing incentives to help sustain the industry.

The agriculture, industrial and environmental sectors will continue to focus on the threats of global population growth and resource scarcity. For the U.S., the acceptance of GM products overseas will continue to be a challenge and is paramount to sustaining its competitive advantage. Other countries are implementing strategies targeting specific biotechnology sectors,

capitalizing on their needs and strengths. For example, Malaysia is investing primarily in the agriculture sector, specifically in palm oil and other Asian specific products.

Finally, the U.S. will experience increased competition in foreign markets as the global biotechnology industry matures. Maintaining the nation's competitive advantage requires collaboration between the biotechnology industry and government to achieving the nation's full surge and mobilization potential. The U.S. is still anticipated to lead the global industry and meet the nation's security requirements in the long-term.

GOVERNMENT GOALS AND ROLE

The government's goals and role in the biotechnology industry derive from the national interests they support. The most critical of these interests are the support of national security and the sustained growth of the domestic economy. National security is achieved through policies promoting public safety, food and energy security, and biodefense. Economic growth requires government policy and funding creating an environment fostering innovation and capital investment in all sectors of the biotechnology industry. In light of the challenges discussed previously, the following policy recommendations address the government's role in ensuring the U.S. maintains its competitive advantage in innovation and implementation.

Funding and Incentives

One of the key challenges for the biotechnology industry is the need for capital investment and financial incentives to sustain innovative product development and approval. While all biotechnology companies seek capital investment, small companies in particular are reliant on angel investors, venture capitalists and government grants for their R&D. Supportive governmental policies are needed to encourage investment for high-risk, high-payoff R&D efforts and to fund small, innovative companies needing investment capital. Government agencies must prioritize government R&D funding to focus on the highest-value technologies for national security and economic interests. The scope and amount of Small Business Innovative Research (SBIR) funding should be broadened to allow venture capital firms to help bolster private investment in smaller, more innovative biotechnology companies using SBIR funds and still struggling to raise capital to survive.

Government policies must recognize that certain R&D, particularly in basic research, requires government funding. Whether conducted at government laboratories or at universities through grants, funding of basic R&D reaps huge returns for the economy and the nation's long-term competitive advantage in the biotechnology industry. Additionally, the government should establish and fund cooperative, industry-government partnership programs in applied research to facilitate bringing biotechnology products to market. Government policies should promote technology transfer that bridges the funding gap between basic research and product development often referred to as the "valley of death."

Globalization of the bioeconomy requires the U.S. to compete for business around the world. In addition to direct government funding, government policies should encourage private investment thorough economic incentive programs. Policies should maximize government subsidies, tax rebates and tax incentives to promote short and long-term investor confidence. Governments at the federal, state and local levels should develop tax incentives encouraging biotechnology companies to establish and retain headquarters, R&D and manufacturing facilities

in the U.S. The U.S. government must provide biotechnology companies, foreign and domestic, the incentives to build and stay in the U.S. To stimulate and support innovative firms, the government should sponsor and fund biotechnology challenges offering cash prizes for demonstrating high-priority technologies that address national security or economic interests.

Sustaining Innovation

Intellectual property and its protection is the single most important asset to a biotechnology firm and the most vital characteristic of the industry in general. In an industry that thrives on new and innovative thinking, researchers, inventors, and investors are motivated by the incentives gained by idea ownership. Strong, predictable and enforceable IP protection is an engine for innovation. Patent protection in particular ensures that those who invest thought and capital into developing new products and processes are rewarded for their efforts through a period of exclusivity of use. The patent system also furthers innovation by allowing others to know and build on or around patented ideas. Without the incentives of patent protection, innovation is stifled and commercializing new products becomes cost prohibitive. Similarly, private investment will retreat from technologies that are unprotected or exposed to unsettled IP protection laws.

A strong, predictable, efficient patent system is a competitive advantage for the U.S. in the global bioeconomy. To maintain that advantage, the U.S. patent system must take several actions. First, the U.S. patent system needs to resolve legal ambiguities as to the scope of patentable biological material. Until these ambiguities are resolved, private investors will be reticent to risk their capital on new biotechnology. Second, the government must streamline the patent application process to ensure the system can keep pace with the rapidly advancing technology. Accordingly, the federal government must adequately fund the Patent and Trademark Office so that it has the capability to thoroughly and responsively adjudicate patent applications. Congress should also seek to reconcile the tension between industry, academia and government over the transfer of technology by establishing a comprehensive framework to facilitate the ease in bringing innovation to the marketplace, while ensuring just compensation for all involved parties. Furthermore, the government should seek to institute a means of compensating patent holders for reduction in actual time to exclusivity due to regulatory hurdles or processes.

Globally, the U.S. must continue to champion IP protection. While patent laws are sovereign issues, global commonality in IP protection reduces risk for global biotechnology firms and promotes global product access. Working through the WTO and multilateral trade agreements, the government should encourage harmonization of global patent laws.

Promoting Comprehensive Regulation

The U.S. needs to develop a national strategy for biotechnology regulation that sets the conditions for industry growth. The strategy should be a comprehensive approach that works to integrate regulation for health and safety, national security, environmental standards, capital investment, taxation, education standards, zoning, monetary policies, IP protection, anti-trust policy, and energy policy to ensure the industry is capable of meeting national objectives and to encourage investment and innovation. With the growth in all biotechnology sectors and the rapid rise of new areas such as bioinfomatics,[46] biosimilar drugs,[47] and synthetic biology,[48] it

becomes increasingly important to have a comprehensive, coordinated and efficient regulatory system. Departmental lead agencies should be designated to improve coordination and execution of regulatory oversight for the biotechnology industry. For example, the biodefense sector would benefit from better alignment of national science and research policies between the Office of Science and Technology, the National Economic Council (NEC), the National Science Foundation (NSF), the National Institute of Health (NIH), and the Center for Disease Control (CDC). Coordination efforts among federal agencies would eliminate duplicative or contradictory rules and regulations and promote regulatory certainty and pathways for innovation development. Regulatory certainty would also improve levels of safety because the industry can know the standards, and the government can better enforce them.

With economic globalization, it has also become more important for biotechnology companies to have regulatory predictability across the global bioeconomy. To further harmonize global regulatory policy, U.S. policy makers should seek multi-lateral approaches to biotechnology regulation, leveraging international organizations like the Organization for Economic Cooperation and Development (OECD), the WHO, and the United Nations to promote policies that are in the nation's economic and security interests.

Developing and Retaining Human Capital

As will be discussed in the essay on human capital later in this report, a key competitive advantage for the U.S. in the biotechnology industry is its talented, educated, and innovative workforce. To maintain its competitive advantage in the global bioeconomy, the U.S. must continue to pursue policies that promote and retain human capital. Specific recommendations to improve U.S. science education and human capital for the biotechnology industry include: working with industry to develop education curriculums that build a science focused workforce; attracting, recruiting and retaining talented math and science teachers; improving America's Kindergarten through 12^{th} grade STEM education level; funding university research programs; developing a communication strategy to encourage more students to enter math and science fields; and partnering with industry to provide extracurricular opportunities and outreach programs.

In addition to the education reforms, the U.S. needs to modify immigration policies to allow long term study and employment opportunities for the highly skilled international biotechnology workforce. Implementation of a high-technology visa and naturalization process would attract and retain talented and innovative biological scientists working in the United States.

Engaging the Public

Public resistance to advances in biotechnology both in the U.S. and abroad often begins with inadequate information or an insufficient decision making framework. The government policy should promote an active and sustained dialogue between the public and industry. Unless the biotechnology industry can overcome public perceptions as well as ethical, economic and social barriers, its full potential will not be realized. The industry would benefit from a coordinated and enduring public information and education campaign that leverages the many resources of academia, non-governmental organizations, professional associations, policy think

tanks, and media institutions to provide credible and accurate information about the biotechnology industry.

Domestically, national public engagement needs to address the benefits and risks of the biotechnology industry. Specifically, it should promote public awareness in a number of areas to include: biotechnology ethical considerations; the benefits of biologic drug therapies, regenerative medicine, and personalized medicine based on genetic sequencing; environmentally sustainable products; and the use of GM crops and organisms to support national food, water and energy security.

The U.S. biotechnology industry must also engage the global public if it seeks to expand the market for biotechnology products. Cultural and historic sensitivities must be considered and addressed to assuage global public concerns of a hegemonic U.S. pushing biotechnology products that are perceived as unsafe or unwelcome. By addressing biotechnology issues in an objective and transparent way, an informed pubic is less likely to overreact to biotechnology safety concerns that can impede development of long-term benefits for all mankind.

ESSAYS ON MAJOR ISSUES

The following essays are presented to highlight three major issues currently facing the industry. The first, *Advances in Bioremediation,* expounds upon the promise of biotechnology to address environmental issues. The *Human Capital and Education* essay highlights the importance of this issue, not only for the biotechnology industry, but also for the nation as a whole. Finally, the *Biodefense* essay provides a clear warning of the risks and opportunities associated with this underappreciated industry sector.

Advances in Bioremediation: Addressing the Environmental Security Threat

The scope and scale of environmental challenges and issues are major national security concerns for the United States. Despite a continually growing deficit and competing budgetary demands, the current administration has demonstrated its commitment to the environmental security of the nation. This renewed emphasis on the environment has spurred the environmental engineering community to find new ways to employ and enhance remediation strategies to clean up contaminated lands, waters and air. The public's desire to use "natural" or "green" treatment technologies for site remediation makes bioremediation a popular choice over other contaminant treatment strategies. Bioremediation is any process that uses microorganisms, fungi, green plants or their enzymes to return the natural environment altered by contaminants to its original condition.[49] Bioremediation is an important emerging market within the industrial biotechnology sector. Furthermore, profound advances in the science of biotechnology make bioremediation a viable and preferred option for addressing global environmental security threats.

Bioremediation as an invention has been around since the late 1960's. The origin of the industry, however, can be traced to 1997 when the first U.S. environmental company, Microbics, acquired the biotechnology company, Xyclonyx, and used their technology and patents for microbes to create an environmental conglomerate for contaminant remediation.[50] For well over 10 years, bioremediation was one of a myriad of remediation options available to the environmental engineering industry. Today, the use of bioremediation is experiencing a renaissance of sorts as the science of biotechnology continues to grow at an exponential rate. A sample of a new discovery and application is described in the following paragraph.

One of the most famous oil spills in history took place near Alaska in 1989 when the tanker, Exxon Valdez, spilled over 10 million gallons of crude oil in Prince William Sound's Bligh Reef.[51] Today, oil spills such as the British Petroleum offshore drill rig, *Deepwater Horizon*, catastrophe in the Gulf of Mexico continue to plague the world's oceans wreaking havoc on aquatic plant and marine life.[52] Over the years, scientific attempts to create an "oil-eating superbug" have not been effective. In his article, *Blueprint of an Oil Eating-Bacterium*, Victor de Lorenzo states that the ability of scientists to better understand the genome of bacteria has mitigated the problems associated with engineering effective, oil-eating bacteria. Scientists have been able to isolate the genome and analyze the proteins involved in regulating the carbon and nitrogen balance in the cells. According to the de Lorenzo article, "The key to improving oil biodegradation in situ is to focus on the nutritional well-being of indigenous marine bacteria by careful manipulation of the carbon/nitrogen/phosphorous balance and by alleviating site-specific environmental hardships. This simple notion- which may signify the demise of the concept of an 'engineered superbug'- may guide better bioremediation strategies in the future."[53] Maintaining favorable conditions for microbial growth is a major limiting factor to the efficacy of bioremediation. Since scientists have a better understanding of cell mechanics, they can now create optimal subsurface conditions to maximum oil degradation by oil-eating bacteria.

It is clear from the example above that advances in the science of biotechnology have created similar advances in biotechnology applications. One simply needs to scan environmental engineering search engines and websites to see the proliferation of new and innovative discoveries in the field of bioremediation. However, because of these new discoveries, the world is becoming more aware of the dangers caused by all types of environmental hazards. As a result, people are becoming more concerned about "environmental security" in the U.S.

In the Millennium Project's environmental security study on emerging international definitions, perceptions, and policy considerations, the term "environmental security" is defined as, "the relative safety from environmental dangers caused by natural or human processes due to ignorance, accident, mismanagement or design and originating within or across national borders."[54] From this definition, one could conclude that the restoration of a contaminated environment to a clean and natural state contributes to regional peace and stability thereby having a positive effect on U.S. national security. Ms. Sherri Goodman, former Deputy Undersecretary of Defense for Environmental Security, would agree with this conclusion as evidenced by her remarks in a Department of Defense (DoD) speech given in 1996 when she stated, "Defense's [DoD's] objective is to understand where and under what circumstances environmental degradation and scarcity may contribute to instability and conflict, and to address those conditions early enough to make a difference."[55] The Millennium Project study goes further to project the most important environmental security threats over the next ten years. Included on this list are the "industrial contamination of air and oceans, and water scarcity and pollution including ground water contamination."[56] As a remediation technology, bioremediation could be a solution to these environmental and national security threats, particularly in maintaining a clean groundwater supply. Moreover, as noted earlier, bioremediation is a "green" solution to these threats.

Pollution levels continue to increase in the U.S. and around the world. Neglecting to address or find solutions for issues associated with pollution will inevitably lead to "instability, disorder, harm or discomfort to the physical systems and living organisms in the ecosystem."[57] Clearly, environmental security is a vital national interest and part of the nation's overall security agenda. Because of limited economic resources to address this threat, scientists and engineers

must find innovative and cost effective ways to clean up the environment. With the immense growth in the biotechnology industry, bioremediation is once again on the forefront of remediation technology.

The on-going, innovative discoveries in the field of bioremediation, combined with continuous federal initiatives, public support for the technology, and its proven cost-effectiveness, will do much to ensure the viability of this particular application of the biotechnology industry. To realize the vast potential of bioremediation, the U.S. should provide significant funding into the science of bioremediation in order to help ensure our environmental security. The future looks bright and the hope for a cleaner, healthier and safer tomorrow are within our grasp. (COL Mark Toy)

Human Capital and Education

Historically, the high levels of education and investment in human capital have been important contributors to improving living standards and the economic success of the U.S. Although the U.S. continues to lead the world in science and technology innovation, the advantage is beginning to decline due in large part to a decreasing number of university degrees awarded to American students in science, technology, engineering, and math (STEM) programs. This is a particularly alarming trend for the economic prosperity of a flourishing U.S. biotechnology industry, which is highly dependent on attracting and hiring the best and brightest scientists.

U.S. biotechnology companies increasingly cite access to a skilled labor pool as one of their most significant challenges.[58] Although the biotechnology industry continues to encourage U.S. educational institutions to increase the production of specialists to support industry needs, there has been a continual shortfall in a variety of areas and expertise creating dependencies on foreign workers outside of the U.S. labor pool. U.S. biotechnology companies are looking for people with both technical and scientific skills, a difficult combination to find. In many U.S. states, hiring challenges result in waits of more than six months to hire entry and mid-level workers, while searches for senior-level executives can require up to a year.[59] In short, there is not enough specialized domestic talent to meet the needs of an emerging and growing biotechnology industry.

Academia recently observed that many U.S. students entering college to study biology and life sciences are disadvantaged by inadequate preparation at the high school level. As reported in 2009, only 28 percent of high school students taking national college admission tests attained a score indicating readiness for college biology.[60] Likewise, international comparisons have revealed that American students do not perform at the level of their foreign counterparts. In 2009, the National Science Foundation ranked the U.S. 20th among all nations in the proportion of students who earn degrees in the natural sciences or engineering.[61] "Once a leader in STEM education, the U.S. is now far behind many countries on several measures."[62] Clearly, if the U.S. is serious about its investment in bioscience and maintaining its status as a leader in innovation, it must focus on the next generation workforce, shoring up high school curriculums. The challenge is to improve the U.S. Kindergarten -12th Grade (K-12) STEM education so high school graduates are better prepared to enter college math and science programs, and successfully enter the biotechnology industry.

A greater effort must be made to initiate K-12 outreach programs. Some excellent programs already exist across the U.S. to generate interest and excitement in biotechnology. For

example, the Broad Institute connects with local high schools and teachers in the Boston/Cambridge area through lab-oriented summer internships, class visits, and semester-long research projects.[63] Also, the biotechnology company, Genentech, has launched an internship program for high school students in California that provides educational scholarships and industry experience.[64] More of these programs are needed to encourage bright young minds to pursue a future in science.

It is in the interest of U.S federal and state governments to create incentives for high achievers to enter the biotechnology industry. The federal government can play a vital role in supporting the biotechnology industry by elevating and addressing educational issues of national concern. Specifically, there are four key areas where federal and state governments should focus: enhancing research and innovation; recruiting and retaining talented math and science teachers; cultivating American talent; and attracting and retaining foreign students and scientists. The federal government needs to increase federal investment in research supported by the National Institutes of Health (NIH) and the NSF, to sustain innovation, biomedical research capacity and scientific infrastructure at universities.[65] Also, federal research agencies should be allocated funding focused on catalyzing high-risk, high-return research to promote breakthroughs in technological innovation.[66] In conjunction with improving the quality and quantity of the STEM teacher workforce, federal and state governments should pursue initiatives to increase the number of U.S. citizens who earn bachelor's degrees in life sciences through scholarships and improve the nation's K-12 education system.[67] Furthermore, the number of graduate fellowships and traineeships supported by existing programs needs to be enhanced at federal science and education agencies including the NSF, the NIH, and the Department of Education. Indeed, since individuals with education in STEM are so important to U.S. competitiveness and innovation, it is critical that visa and immigration policies be reformed to allow America to attract and retain top foreign talent. Specifically, government policy changes are needed to create efficient pathways to U.S. citizenship and permanent residency for top international students and outstanding scientists on exchange or work visas, and to allow their full participation in the conduct of unclassified research.[68]

Other nations are increasing investments in biotechnology-related research and education, making themselves very attractive in the global competition for talent. For example, Singapore continues to invest billions of dollars in state-of-the art biomedical science research and teaching facilities, and is aggressively recruiting the world's leading scientists.[69] Ireland has developed an effective national education and training strategy to produce workers for its biotechnology manufacturing facilities – infrastructure built and paid for by global companies.[70] Also, China has increased its financial commitment to scientific R&D, established highly competitive university programs, and is actively recruiting students back into its own workforce. "China wants Chinese scientists to return to their homeland, and is offering salaries that are competitive with US pay. This 'reverse brain drain' makes the need to train new scientists in the U.S. even more critical."[71]

Current trends indicate America is failing to prepare students for higher education in the math and science domains – a key ingredient for developing the future biotechnology workforce. As noted recently by James Greenwood, President of Biotechnology Industry Organization (BIO) and member of the Board of the Biotechnology Institute, "The prospect of the U.S. losing its competitive edge in student achievement and the subsequent skills of our future workforce is a matter of significant concern."[72] The nation's talent advantage in the biotechnology industry will erode unless employers, government, and educators work together to maintain it. Formal

strategies need to be developed and resourced to produce the next generation of scientists, medical professionals, engineers, mathematicians and entrepreneurs. Otherwise, the U.S. will lose ground to its global competitors in attracting and retaining human capital and promoting corporate growth in the biotechnology industry.[73] (Col Tom Endicott)

Biodefense

"Obama Gets 'F' on Stopping Spread of Weapons of Mass Destruction."[74] This unflattering headline summarized a nineteen page report card issued in January 2010 by the bipartisan Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. The assessment was disconcerting, specifically in the area of biological threats. U.S. public policy must address the interrelated social, political and economic issues affecting our infant biodefense industries in order to meet the desired long-term strategic goal of reducing the biothreat risk to America.

The lexicon of terms associated with biodefense is vast and often overlapping.[75] Regardless of the current semantics in terminology, a natural, accidental or deliberate release of a biologically infectious disease is the most likely threat to the public health security of the U.S. Our lack of capabilities to recognize, respond and recover to biological events is our greatest vulnerability.[76] Addressing this shortcoming requires an industry with the capacity to meet both current and future needs. The small industrial base of biodefense firms can work with our government to find detection methods, preventative medicines and corrective remedies to counter biological threats in order to improve national security. This partnership can assist in closing the gap in protecting the public from evolving and expanding biothreats. Growing the domestic biodefense industry requires active policy measures to assist in overcoming existing social, political and economic barriers.

Mixed signals from public policies on federal research negatively impact the biodefense industry. In August 2009, the Director, Office of Science & Technology Policy released the FY2011 Science and Technology priorities. The focus of scientific discovery and technological innovation was articulated in the memorandum to focus on applied research strategies.[77] The following month, the National Economic Council released the Strategy for American Innovation. The strategy for investing in the building blocks for innovation listed the restoration of American leadership in fundamental research as a cornerstone for sustainable growth and quality jobs.[78] These mixed signals between fundamental and applied research priorities impair industry from attaining the talent and building the infrastructure needed to support meeting these conflicting national objectives.

Another area of concern for the biodefense industy is policy gaps. Bioterrorism is a national security issue, but it has been difficult to translate national security policy into the domain of the Department of Health and Human Services (HHS). The policy gap is that traditional "guards, guns and gates" processes are unlikely to succeed in a rapidly expanding, private-sector led global biotechnology industry. Adding national security to public health will be difficult, but these regulations must be established to protect potentially hazardous biologics moving in global supply chains. These policies will support biodefense projects like the Biowatch airborne biological agent warning program and the Project Bioshield initiative.[79]

A natural, accidental or deliberate biological attack against the U.S. is the most likely threat our nation will face in the foreseeable future. Growing the capacity of the domestic biodefense industry is essential to meeting our national goal of reducing the risk biothreats pose

to our society. To attain this goal, changes to social, political and economic policies and regulations are needed to provide incentives to the biodefense industry. Surviving biological threats will require effective detection methods and the rapid development and commercialization of preventative vaccines and corrective medicines by the biotechnology and biodefense industry to protect our citizens. (CDR Jeff Hickox)

CONCLUSION

The biotechnology industry is and will continue to grow as a strategically important capability supporting U.S. national security interests and stimulating economic growth. The industry continues to make dramatic advances in healthcare, agriculture and industrial applications with the potential to significantly impact many other strategically important national industries. Whether preventing pandemic diseases, addressing critical global food and water security challenges, or developing new sources of renewable energy, modern biotechnology represents a powerful tool for solving the world's most enduring problems. With this tremendous potential, also comes the responsibility of mitigating the risks associated with this emerging science. Additionally, the industry must deal with the moral and ethical issues that accompany modifying living organisms. The challenge for government and industry is to maximize the benefits of biotechnology while maintaining the safety and security of society and the environment.

For the U.S. biotechnology industry, maximization of benefit requires maintaining the its current competitive advantage. The U.S. is the world leader in the global bioeconomy with almost half of the market share in all sectors. This dominance derives from its innovative environment, and its ability to transform ideas into commercially viable products and services. Biotechnology innovation in the U.S. is shaped by its robust public and private capital investment, the strength of intellectual property protection, public acceptance, a highly educated work force, the synergy of bioclusters, and an entrepreneurial culture that embraces the risk of failure.

Recognizing the growing importance of biotechnology, many countries, primarily in Europe and Asia, are making considerable investments in infrastructure and human capital to increase their biotechnology capability. These countries recognize the trend of a growing global market and are positioning themselves to compete with the United States. Unlike the U.S. which is in the growth phase of the biotechnology industry life cycle, most of these countries remain in the introduction phase. Countries have identified the necessary components of a viable biotechnology industry, but lack key components such as sufficient human capital, technological expertise, adequate IP protection, or capital investment. As these countries develop these components, their competitiveness will increase.

In light of the trends toward limited access to funding, slowing industry growth, and increased global competition, the U.S. biotechnology industry must take proactive steps to maintain its leadership position, particularly actions that sustain our competitive advantages in innovation and the ability to effectively bring products and services to market. Specific recommendations address five major areas: (1) continuing robust funding for basic R&D and creating incentives promoting private investment; (2) championing strong IP protection across the global industry; (3) promoting an agile, proactive, comprehensive, and harmonized domestic and global regulatory framework; (4) reinvigorating the U.S. education system focusing on science and math disciplines and modernizing U.S. immigration policy to meet human capital

requirements; and, (5) engaging the media and public regarding the processes, benefits and risks of biotechnology to build the trust necessary to realize the full potential of the biotechnology industry.

By addressing these current and future challenges to the industry, the U.S. will be able to grow and maintain dominance in the domestic and global markets. This will not only serve the national interests of security and economic growth, but also dramatically improve the living conditions for all mankind while protecting the environment for future generations.

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