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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 2011

ABSTRACT: Biotechnology is a global industry that leverages the power of business and science to develop innovative solutions to address some of the most daunting challenges of the 21st century. The strategic significance of the biotechnology industry is firmly established by its ability to address these challenges of increased demand for health care, food, energy, and other diminishing natural resources. Whether it is a new molecule for curing breast cancer, a corn seed resistant to disease and drought, or a method of using algae to produce petroleum, the U.S. biotechnology industry's position as the global leader remains unchallenged. It continues to distinguish itself in its ability to establish centers of innovation, fund the development of breakthrough technologies and applications, and to translate those scientific discoveries into global products and services. In 2010, the U.S. biotechnology industry's revenue of $92.4B and near term projected growth rate of 9.4% was a direct result of its agility and responsiveness to emerging demand. While the recent economic downturn resulted in global industry consolidations, reduced investor confidence, and created increased market volatility, the U.S. biotechnology industry remains vibrant and healthy.

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VISITS

Domestic:
Biotechnology Industry Organization, Washington D.C.
Food and Drug Administration, Washington, D.C.
National Institutes of Health, Washington D.C.
Harvard Stem Cell Research Institute, Children's Hospital, Boston, Massachusetts
Broad Institute of MIT and Harvard, Cambridge, Massachusetts
Massachusetts Biotechnology Council, Cambridge, Massachusetts
Charles River Laboratories, Wilmington, Massachusetts
AMGEN, Cambridge, Massachusetts
Edgewood Chemical Biological Center, Aberdeen Proving Grounds, Maryland
Abbott Laboratories, Abbott Park, Illinois
Institute for Genomics and Systems Biology, Chicago, Illinois
Center for Urban Environmental Research & Policy, Loyola University, Chicago, Illinois
Agricultural Research Service, U.S. Department of Agriculture, Beltsville, Maryland
Codexis, Redwood City, California
SRI International, Menlo Park, California
Solazyme, South San Francisco, California
Burrill & Company, San Francisco, California
Fluidigm, San Francisco, California
Bay Bio, South San Francisco, California
Takeda, South San Francisco, California
QB3 Garage, San Francisco, California
Gen Probe, Inc., San Diego, California
Nuvasive, Inc., San Diego, California
Life Technologies, Carlsbad, California
Sapphire Energy, San Diego, California
La Jolla Institute, La Jolla, California
University of Maryland Baltimore, BioPark, Baltimore, Maryland
Institute of Marine Biotechnology, Baltimore, Maryland
Human Genome Sciences, Rockville, Maryland

International:
Agency for Science, Technology and Research, Singapore
Maccine Pte Ltd, Singapore
Singapore Economic Development Board, Singapore
Abbott Laboratories, Singapore
U. S. Embassy, Kuala Lumpur, Malaysia
Biotech Corporation, Kuala Lumpur, Malaysia
Malaysian Agricultural Research Development Institute, Kuala Lumpur, Malaysia
Stempeutics, Kuala Lumpur, Malaysia
Inno Biologics, Kuala Lumpur, Malaysia
Myagri Group, Kuala Lumpur, Malaysia
U.S Embassy, Bangkok, Thailand
National Center for Genetic Engineering & Biotechnology, Bangkok, Thailand
Beijing Pharmaceutical Group, Beijing, China
Merck, Sharpe and Dohme, China, Beijing, China
Sino-American Laboratory, Beijing, China

BIOTECHNOLOGY: A Pathway to the Future

"The first century of the new millennium will not only belong to information and communications technology, as we are often led to believe, but also to biotechnology, and its immense potential to contribute to human and animal health, agriculture and food production, manufacturing and sustainable development"[1]

- *Ben Ngubane, South African Minister of Arts, Culture, Science, and Technology*

INTRODUCTION

Today in a laboratory in San Francisco, a group of scientists huddles around a microscope, on the verge of developing a new molecule capable of curing breast cancer. At the same moment in Amsterdam, biologists test a form of algae capable of creating petroleum, while in Rio de Janeiro, genetic engineers produce corn seeds capable of growing in hostile climates, with yields exceeding traditional crops. Biotechnology affects every aspect of human existence. From food to fuel to healthcare, from tactical upgrades of existing science to game-changing breakthroughs, biotechnology promises to play a role in every facet of life on earth.

Biotechnology blends science and technology to alter living or non-living materials as well as the parts, products and models thereof, for the production of knowledge, goods, and services. The U.S. industry that has grown up around this blend is diverse and vibrant, running the gamut from small start-up companies to large, established firms. While the industry traces its roots to the early 1970's with the advent of genetic manipulation, it is only now emerging on the world stage with the real prospect of providing solutions to some of the most difficult challenges of our time – global food security and safety; spiraling healthcare costs and personalized medical demands; and, the need for alternative energy sources as well as energy independence.

The biotechnology industry in the United States promotes and advances three key enduring national interests for the United States: security, economic prosperity, and stability in the international order. This paper will define the industry through its structure, conduct, and performance. It will identify key challenges influencing the overall health of the U.S. industry as well as address the key role government plays in all aspects of the industry's efforts to create economic as well as societal value. A set of policy recommendations will follow an overview of key issues in ethics, biofuels, emerging trends and the industry's outlook to 2016 and beyond.

THE BIOTECHNOLOGY INDUSTRY DEFINED: STRUCTURE

Biotechnology is a complex producer industry supplying the necessary technology and methodologies required by other industries to develop products that create value for both suppliers and consumers. The biotechnology industry consists of large multinational firms, entrepreneurial firms, public and private research entities, dedicated biotechnology investment companies, bioinformatics companies, and academia. Firms in the global biotechnology industry range from dedicated commercial biotechnology firms to research and development (R&D) firms and multinationals with biotechnology as only one part of a multifaceted business model. Among the core biotechnology commercial and the R&D firms, there are three broad tiers within the biotechnology industry: dedicated, multifaceted, and supporting/recipient firms.

A dedicated biotechnology firm's predominant activity involves the application of biotechnology techniques to produce goods or services and/or the pursuit of new biotechnology discoveries.[2] Multifaceted biotechnology firms attribute only a portion of their total activity to biotechnology. Supporting/recipient firms receive, use, market, support, translate, and/or facilitate the commercialization of biotechnology products and services, but they themselves are not biotechnology firms. Figure 1 illustrates the diverse nature of the biotechnology industry.

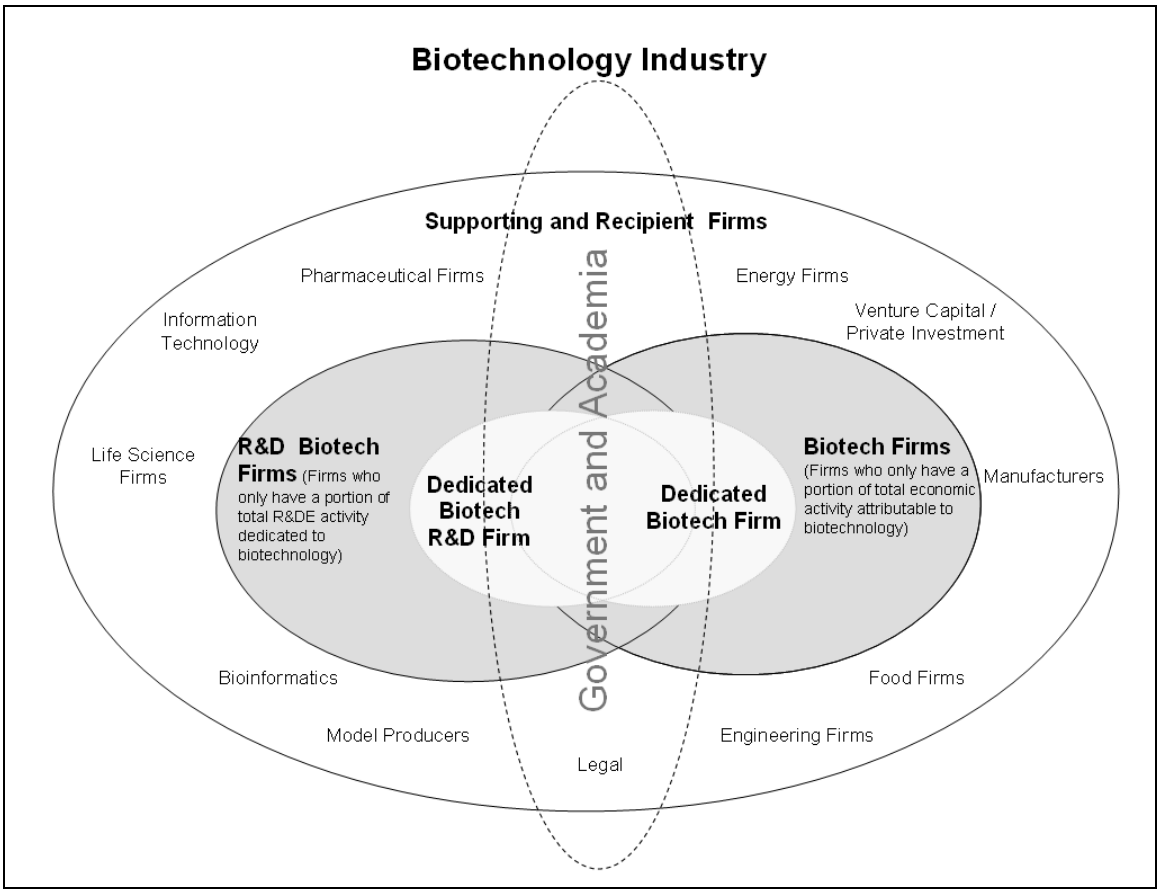

Figure 1. The US Biotechnology Industry[3]

Industry Interaction with Academia and Government – The Triple Helix. The U.S. Government plays a fundamental role in the biotechnology industry. It is a major customer of biotechnology products and services, sets the policy and legal frameworks intended to spur innovation and commercialization, invests in public goods such as purely scientific as well as commercially viable biotechnology R&D, and provides the regulatory authorities to ensure the safety and efficacy of commercial products. The U.S. Government balances its relationships with academia and industry in an effort to deliver safe and effective biotechnological goods and services in a timely manner in order to create economic and societal value. This "Triple Helix" model of innovation – government, academia, and industry working together – captures the multiple interactive relationships found in the biotechnology industry.[4] The robust nature of the Triple Helix found in the United States is a distinct strategic advantage in a highly competitive global industry.

Industry Structure. Biotechnology as an industry is relatively young and remains firmly in the growth phase (See Figure 2). Human health technologies currently hold a dominating market share, principally through biological drugs. However, multiple market segments are experiencing high levels of growth, which will likely undercut the dominance of human health as an industry focus. Biotechnology research typically involves a high-level mix of scientific theory and commercial risk. As such, it is heavily reliant upon funding by a multitude of sources, including government, universities, venture capitalists, and non-profit organizations. It remains a stark reality that much of the science of biotechnology never makes it to the market. The hurdle to commercialization is high with many attempting the leap but with few succeeding. The commercial development phase, which accounts for more than half of all R&D spending, seeks to refine the technologies or processes produced by research into usable products. The private sector carries out most of this development effort and generally orients it toward the manufacturing of commercially viable products. Without marketable products, firms will simply not survive to innovate another day. Current revenue must then in large part fund R&D, and it comes from various sources. Product sales, such as from therapeutic drugs, agricultural services and technologies, and industrial applications generate the majority of industry revenue. Other secondary revenue sources include government funding, consulting fees, the sale of clinical services and venture capital or angel investment. Together, these secondary sources make up only about 20% of total industry revenue. Interest and royalty licensing revenues account for about 5% and 3% of total income, respectively.[5] The picture that emerges is of an industry heavily dependent on current sales to generate the funds needed to finance R&D for future discoveries and thus continued success.

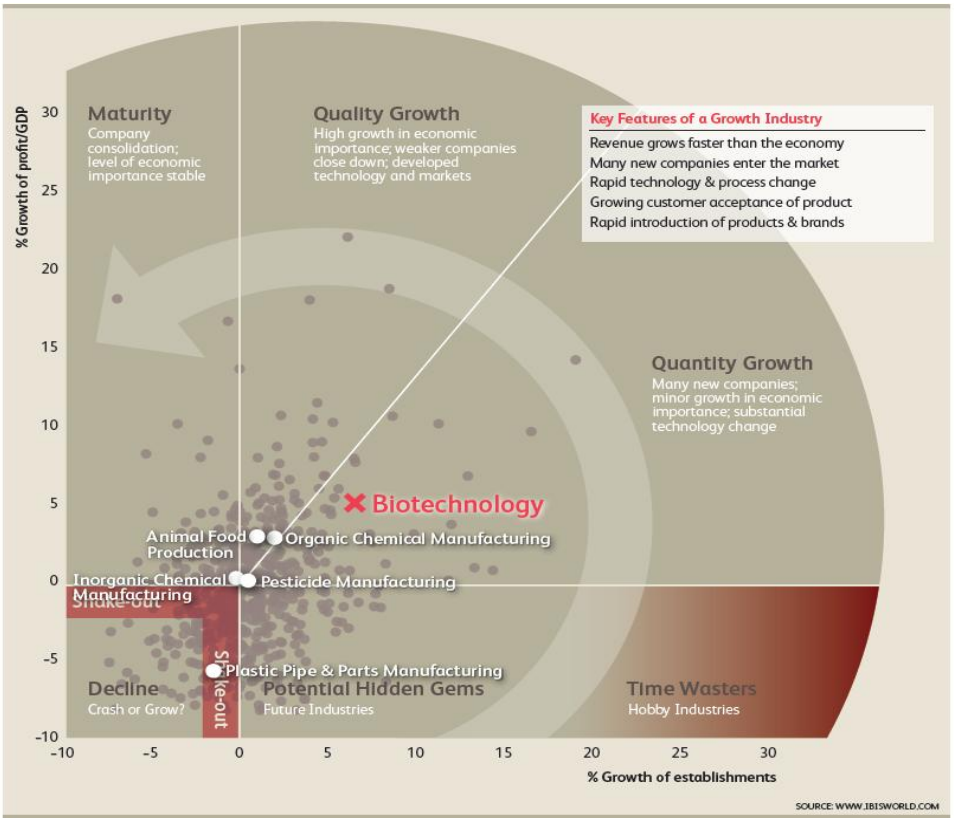

Figure 2: Biotechnology in the Life Cycle Stage[6]

Biotechnology Market Segmentation. The biotechnology market consists of segments encompassing the development, manufacturing and marketing of products based on advanced biotechnology research. The market value of any segment reflects the revenues of companies from product sales, licensing fees, royalties and research funding. Biotechnology products and services cover five main areas: human health technologies; agricultural and aquacultural technologies; industrial technologies; animal health, marine, and terrestrial technologies; and, environmental remediation and natural resources recovery, as represented in Figure 3.

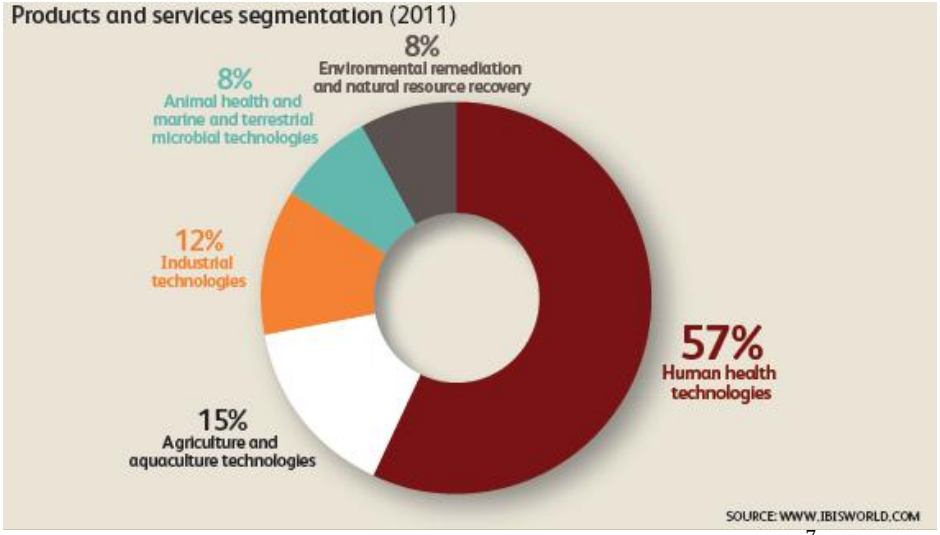

Figure 3: 2011 Biotechnology Market Segmentation[7]

Biotechnology Industry Status. Thanks in large part to the diverse segmentation of the biotechnology market, biotechnology as an industry writ large is still in a strong growth phase. It also and has a vast potential to create value in both products and services well into the future across all market segments. While there are many areas of life and bioscience research that have yet to gain large-scale public acceptance domestically and internationally, the public has shown great willingness to embrace biotechnology products and services. The U.S. public places great faith in the regulatory establishment's ability to allow only safe and efficacious products and services to flow to consumers. That flow of products and services is the end result of massive amounts of private and public investment, long product development timelines, a high failure rate, considerable expense involved in R&D at every level, and heavy regulation. All of these realities form high barriers to entry for start-up companies and significant challenges for the continued viability of smaller companies. Additionally, the risk of substitutes through products such as biosimilars,[8] disruptive technologies creating new markets that also threaten to destroy or undermine existing markets, and global competition create a high-risk environment even for medium and large sized companies. The industry accepts a high rate of failure for both products and companies. It has also adapted to this environment by increased outsourcing of R&D and risk through partnerships, mergers and acquisitions, successfully extending intellectual property protection, and increased investment in emerging markets.

THE BIOTECHNOLOGY INDUSTRY DEFINED: CONDUCT AND PERFORMANCE

All of that risk also brings with it great rewards for the U.S. biotechnology sector. With 2010 revenues at $92.4B, and a current market capitalization of $1.14T, the industry is projected to grow at 9.6% over the course of the near-term future.[9,10] This will far outpace anticipated real GDP growth in the U.S. and explains why in addition to the clear societal value advances in biotechnology bring, the profit motivation for the U.S. private sector remains well place. While the industry is credited with creating approximately 7.5 million jobs in the U.S. and hundreds of innovative value-creating products over its lifetime, it is critical to reiterate that the majority of biotechnology companies are never successful[11]. They never market a product, they never turn a profit, and they never survive more than a few years. While these two points on the conduct of the industry may seem at odds with each another – great success for some and abject failure for most – they are both characteristics of an industry in the growth stage of its lifecycle.

Investments and Revenue. As an industry firmly rooted in the growth stage and with a heavy reliance on science, biotechnology ultimately depends on R&D investment to drive innovation and thus fuel future revenue growth. The recent economic downturn constrained such investment and increased revenue volatility. Reductions in available capital forced a delay in research efforts and pushed firms to relentlessly pursue efficiencies over the course of 2008 and 2009. These sought-after efficiencies included efforts to boost revenue by outsourcing R&D to smaller U.S. firms and global pre-clinical research divisions, both of which compete on lower overhead costs; by increasing mergers and acquisitions as a way to in-license new technology and products (see Figure 4 which shows consolidation within the pharmaceutical sector over the last few years); and, by focusing late-stage R&D investments on technology with the greatest potential to extend current market shares through "evergreening"[12] existing patents.

Figure 4: Drug Industry Consolidation

Influence of Risk, Regulations, and Incentives on Bioclusters. One industry response to the challenge of a high barrier to entry for firms and products created by risk, regulation, and competition has been to seek refugee in bioclusters. Certain regions within the U.S. have sought to leverage advantages in human and financial capital through the establishment of bio-technology clusters to co-locate R&D facilities, entrepreneurial start-up companies, venture capitalists, and academic institutions. Additionally, efforts by states to encourage R&D, such as California which established its own fund for stem cell research when the U.S. Government ended its funding, have helped the industry minimize some challenges. Somewhat surprisingly, concentration within the industry still remains low – despite many recent mergers and acquisitions – with hundreds of small companies still competing for the development of new biotechnology intellectual property and products. Thrown into the mix with this highly technical and competitive industry, heavy government regulation presents another challenge to industry actors. This is particularly true in the pharmaceutical segment. Comments from pharmaceutical and industry representatives consistently cited a lack of predictability in government regulatory oversight and health care reform uncertainties as the greatest challenges affecting their investment and development decisions. Given such unpredictability, it is no surprise firms choose to compete in less risky/lower margin areas, such as the emerging field of biosimilars instead of consistently pursuing new product development.

Megatrends. The stark risk and reward nature of the industry lives in the context of megatrends in health, food, and fuel which drive the industry on a macroeconomic level. The strategic direction of the biotechnology industry reflects unmet demands in the medical, agricultural, energy and environmental sectors. Aging populations and public health policies will shape demands for medical care, creating new markets and opportunities for biotechnology applications. Increasing populations and reductions in arable land will shape global demand for food, necessitating higher output as well as disease/pest resistant crops and animals. Constraints on oil, gas, and coal production and increased attention to environmental impacts are creating a demand for the bioengineering of energy sources and remediation compounds.

Another overarching megatrend is how large government deficits and related public pressure to cut spending will affect the biotechnology industry. Reductions in regulatory agency budgets could deliver a two-prong blow: reducing government funding for basic science and research and reducing regulatory staff, creating delays in approving commercially viable products. Government's failure to play an equal role in the Triple Helix along with academia and industry could prove to be the ultimate barrier to success few firms can manage.

GOVERNMENT GOALS AND ROLES IN THE INDUSTRY TODAY

Many levels of the U.S. Government plays key role for the biotechnology industry from investing in basic science to setting strategic-level policy direction to allowing companies to market their products and services. The government's ultimate role though is to promote the growth of the industry, to create economic value, and to enhance the public good. It must tread the fine line between fostering ground-breaking innovations while ensuring the safety and efficacy of biotechnology products. Compounding the complexity of its involvement, government is also a consumer of biotechnology products such as biologic drugs for biosecurity, biodefense, and biofuels. The outcome of this balancing act directly affects our national security

through its effect on our economic prosperity, the health and future of the industry, and the well being of our citizens.

The key government agencies regulating the industry are: the Food and Drug Administration (FDA) with authority over food and bio-pharmaceuticals; the Animal and Plant Health Inspection Service (APHIS) with authority over bio-agriculture; and, the Environmental Protection Agency (EPA) with authority over appropriate bio-industrials associated with energy and the environment. These agencies must daily walk the fine line between the benefit of any biotechnology product or service and its potential danger to the public and the environment.

Beyond its daily work, government at the macroeconomic level plays a key role in setting the stage for a healthy and vibrant biotechnology sector in three ways: protecting intellectual capital; providing funding for research and development; and, providing financial incentives to stimulate innovation. The 1980 Bayh-Dole Act allowed researchers and their institutions to profit from discoveries based on government funding. This helped foster a leap in technology transfer from the lab to the market from just a few cases before 1980 to over 4,000 by 2005. [13] Simply put, the legislation provided the stimulus to translate basic science into commercial applications. The 1984 Hatch-Waxman Act provided additional incentive by barring "generic manufacturers from using brand manufacturers' data in their Abbreviated New Drug Applications for five years for new compounds and three years for new uses of existing compounds."[14] This data exclusivity for biologic drugs was increased from 5 to 12 years by the 2010 Patient Protection and Affordable Care Act (PPACA) in recognition of the longer approval process for biologics.

Many Federal government agencies also play strategic roles by providing substantial funding. The National Institutes of Health (NIH) have provided between $28 and $31 billion per year over the last 6 years by awarding grants to research institutions to improve health and fight disease.[15] The Biomedical Advance Research and Development Authority, part of the Department of Health and Human Services (HHS), provides funding to support medical countermeasures such as vaccines for bio-defense. Small Business Innovative Research grants from NIH, the National Science Foundation, and the Department of Defense (DoD) are also sources of funding. Finally, the Department of Energy and DoD made substantial investments in the biofuels sector.

While basic funding is important to the long-term health of the industry, no firm can survive the short term without commercializing products and services. Here again, the government can and does play a part in providing incentives to drive commercialization, almost always the most difficult step for any company large or small. For example, the NIH and DoD have entered into cooperative research and development agreements with industry to accelerate the translation of federally developed technology into commercial products. The 2010 PPACA introduced Therapeutic Discovery Project Credits to provide small companies tax credits to offset the cost of first stage clinical drug trials. Additionally, HHS inaugurated two new programs in 2010 to "offer $2 billion to spur new facility construction and drug development."[16] Finally, the success of bioclusters in San Francisco, San Diego, Chicago, Baltimore, and Boston is due not just to the confluence of academia and industry but also to targeted federal and state government incentives.

It is often easier for government to identify the societal and economic value of biotechnology than it is to find practical ways to boost the vibrancy of the industry. The U.S. Government has shown a notable dedication to promoting the industry from funding basic research to providing intellectual property protection and financial incentives. Industry and academia need this active involvement for without it much of the fundamental science and innovation they are able to create would never reach consumers, add to the general public good, or contribute substantially to the economic strength of the United States.

CHALLENGES

Challenges lurk around every corner in biotechnology and they must be addressed for individual firms, both large and small, to thrive and ensure the strength and vibrancy of the industry for the foreseeable future. The overarching challenges fall into three key areas: the availability of R&D funding to fuel innovation, the vagaries of the regulatory process, and the commanding influence of public sentiment in a democracy.

Changes in Sources of R&D Funding. As previously noted, the U.S. Government plays a direct role by providing funding for scientific discovery through tens of billions of dollars in annual grants. From the private sector side of the R&D funding equation, however, the recent past has seen dramatic changes. Before 2007, private sector R&D funding came largely from stock and bond issues, venture capitalists, or mergers and acquisitions by larger companies. The global economic downturn has changed this previous model for such investment in biotechnology, especially in the biopharmaceutical sector. Both larger companies and venture capitalists became more risk averse due to declining revenue in the wake of massive drops in consumer spending in 2008 and 2009. As a result, the investment focus for both groups has largely changed from funding start–up companies in the early stages of development to a concentration on those with products much closer to being ready to enter the market. The emphasis has shifted then from a longer term view which favored substantial R&D to one in which the ability of marketable products to produce revenue has taken precedence. This shift has implications for the appetite of many firms to fund development during the period often referred to as the "valley of death," – the void between discovery in the lab and the marketing of an approved product. The average cost of walking a new pharmaceutical across this valley is at approximately $1.2B over a 10-year timeframe. It is unclear if a general economic recovery will mean a shift back to a private sector focus on long-term R&D funding as opposed to the need for short-run moneymakers. If such a return to research funding does not occur, this will likely have long-term negative implications for the ability of U.S. industry to innovate.

Regulatory Environment. One challenge often citied by industry is the government's inability to keep its regulatory apparatus up to date with the speed of innovation in the biotechnology. Gaps in policy and sometimes chronic inconsistencies in the application of regulations can create undermining uncertainty for industry. The overlapping regulatory approval processes of the FDA, APHIS, and the EPA have become bottlenecks in the views of many, often hindering the marketing of innovation and the development of new biotechnology products. Industry sources consistently cite the lack of consistency in personnel, requirements, and ultimately policy on the part of the FDA, APHIS, and EPA as the largest roadblocks to commercialization. Ever-changing reviewing officials, shifting standards for approval, and

increasingly long review cycles are the chief complaints cited. This domestic bureaucratic delay coupled with the lure of decreased regulatory burdens, tax benefits and profit incentives provided through global markets could mean sales, production, and jobs will leave the United States.

The global market angle presents in and of itself a difficult dilemma for the regulatory agencies for they must continue to weigh a product's risk against its benefit. While industry (and to some degree academia as well) must remain fully cognizant of the international biotechnology environment, U.S. regulatory agencies cannot abdicate their core responsibility to American consumers to approve only safe and efficacious products in order to compete with more minimal regulatory environments overseas.

Influence of Public Sentiment. Never to be overlooked in a democracy is the public's role. While the Triple Helix does not specifically mention the public, its role is there in all three academic, industrial, and governmental roles. In addition, globalization and the proliferation of access to information have shifted society's perception of science and technology and their abilities to help us address the world's problems. The unprecedented pace of development over the past three decades has challenged theological, societal, and social norms, which to previous generations probably seemed immovable. In biotechnology, the public plays a defining yet often understated role as the industry's profitability is more sensitive than most to the influence of public opinion.

Survey data analyzed by the National Science Foundation has identified a positive correlation between scientific advances and the public's willingness to accept their promises. In the U.S., support for and moral acceptance of embryonic stem cell research grew from 35% in 2001 to 48% in 2003 and had reached 57% by 2008[17]. In a similar albeit less dramatic shift, public opposition to human cloning has moved from over 90% in 2003 to 72% in 2008[18]. While subject to enormous outcry in some international circles, genetically modified (GM) food products remain one of the least controversial biotechnologies in the U.S. with a consistent level of support of more than 80% over the past decade[19]. Overall, "global adoption of biotechnology crops continues to rise with 29 countries now growing biotechnology crop varieties"[20] and many more using GM products.

While biotechnology has provided incredible advances in the agriculture, medicine, energy and environmental sectors, any new step must ultimately be accepted by a public potentially buffeted by the pace of advances. The challenge of maintaining public support for game-changing technologies remains a factor in defining the landscape in which scientific and commercial actors operate. All too often, however, there is a "lag effect" between a democracy's debate and advance of science. The two are unlikely ever to be well synchronized. For industry, this means government regulation might be out of step with science as the society underpinning representative government struggles to comprehend the nature and pace of change. While the government plays a central role in funding biotechnology research and development, public sentiment about the value of biotechnology ultimately determines long-term public funding.

ESSAYS ON BIOTECHNOLOGY ISSUES

There are a multitude of biotechnology subjects closely tied to the vibrancy and health of the U.S. industry which could be addressed at length in any study. Several key subject areas – ethics, biofuels, and a look at emerging trends – merit particular attention.

I. The American Ethical Framework For Biotechnology

Ethics, Morality and Public Opinion. Ethics is a branch of philosophy, often tied to cultural norms and standards of conduct, that seeks to answer questions about moral issues. Bioethics is specifically interested in the conduct and thinking of medical and public health professions as well as policymakers. Some of the more controversial bioethical issues include in vitro fertilization, human therapeutic cloning, and embryonic stem cell research. The U.S. Government has attempted to strike a balance between innovation/value creation in the biotechnology industry and public concerns about the ethical implications of such policy decisions. An enduring ethical framework ideally considers equally the roles of public opinion, government, and science. Public opinion is the aggregation of individual attitudes held by the adult population. Such public opinion is manifested in a representative republic through the election of representatives who themselves reflect the views of the majority. Public opinion is thus one of the most important factors determining the parameters of biotech policy and debate.

Science, Industry, and Government. The science that drives the innovation necessary to make biotechnology a successful sector requires intellectual freedom, objectivity and independence balanced with a strong sense of the ethical values found in society writ large. There is a full spectrum of self-regulating ethics councils in the U.S. led by scientists to ensure ethical practices. Given the heavy capital costs of bringing even a single drug to market, tension in the private sector between ethics and the drive to profits should not be surprising. Government has a major role in ensuring this tension does not endanger the public while also maintaining as open an environment for innovation and ultimately profit as possible.

Ethical Principles, Shared Values, and Self-Interests. The relation of the government to the other players in the biotechnology industry is described in the diagram on the following page (See Figure 5). The framework highlights key principles and shared values essential in the relationship between industry, science, and public opinion and introduces the concept of government as a supportive partner. At the heart of the framework lies the ultimate aim of safety and efficacy.

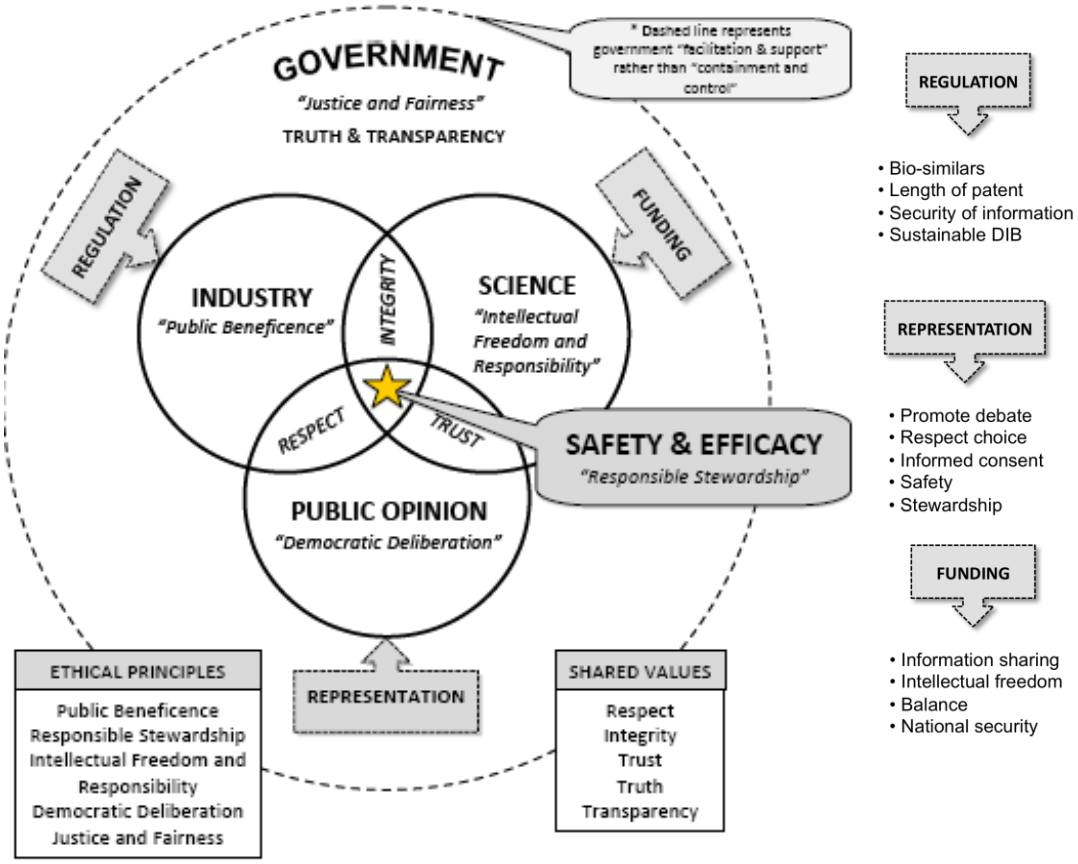

Figure 5: Ethics framework for biotechnology

Democratic Deliberation to Inform the Public and Policy. The principle of democratic deliberation provides a method for government to balance these competing self-interests. It informs the public and involves it in making policy. Such deliberation reflects an approach to collaborative decision making that embraces respectful debate of opposing views and active participation by citizens.[21] This reflects the intention of the U.S. system of government by considering the interests of multiple constituencies. The disadvantage is the "lag effect" that occurs when government attempts to regulate an industry that innovates faster than policy makers can respond to. The ultimate advantage of democratic deliberation is the creation of sustainable policy supported by the public. It is also consistent with the fundamental beliefs upon which U.S. societal values draw. It informs policymakers as to the ethical boundaries between risk and benefit. This has created an environment in which the industry can remain innovative and forward looking while finding sustainability in an ethical policy framework acceptable to the broadest possible measure of society's views and values.

II. The Future of Biofuels

"The development and adoption of new biofuels is a national security goal as well as an economic goal. It's about getting to that point where you have enough independence in what you create that those who would do you harm no longer have that tool available to them.

The U.S. can start to make the rest of the world anxious about providing us oil instead of seeing it as a tool that can be used against us."[22]

- Dallas Tonsager, Under Secretary for Rural Development, USDA

The U.S. produces only 10% of all petroleum, yet it consumes 23%[23]. A total of 26% of petroleum used by the U.S. comes from OPEC member countries[24]. America is addicted to oil and this oil addiction is not only a threat to our economy and environment, but more significantly it is a threat to our national security. The addiction has been worsening for decades. In 1970, we imported 24% of our oil, and today we import more than 65%[25]. The 2010 U.S. National Security Strategy cites the reluctance to move away from fossil fuels as a consistent contributor to our energy dependence and notes that it will likely continue to undermine our national security[26]. Total global oil consumption will increase from 86 million barrels a day in 2007 to nearly 111 million barrels per day in 2035, nearly a 30 percent increase.[27]

Through the application of biotechnology, biofuels offer a viable option to reduce fossil fuel demand and therefore is a consideration in achieving energy security and independence in the foreseeable future. The pursuit of biofuels is a strategic issue because it represents a bridge to future alternative energy technology or sources, offering an opportunity to reduce U.S. dependence on foreign oil sources in the short term. The development of alternatives to oil is especially critical to the DoD. As larger portions of the nation's declining defense budgets are consumed by higher personnel and healthcare costs, it is essential that the cost of fuel not be tied to the highly unstable oil producing countries. Failure to reduce U.S. dependence on foreign oil will result in less flexibility in replacing aging weapons systems and defense infrastructure.

The biofuels industry faces four broad challenges: lowering the cost of production to create an "acceptable" price per gallon of fuel, increasing the supply of feedstock available to manufacture biofuel products, building the infrastructure that will produce, distribute and consume biofuel products, and creating a sustainable and renewable biofuels business model. The industry cannot meet these challenges alone. The challenge must be addressed by coalitions and partnerships involving the energy, biotechnology, transportation, and agriculture industries; strong support and a long-term strategic commitment from the government; and, broad public and business consumer acceptance.

One attempt to meet these broad challenges is the U.S. national goal of tripling the 12 billion gallons of biofuel the U.S. currently produces to 36 billion gallons by 2022. In addition, the DoD, specifically the U.S. Navy, has embarked on a mission to use a 50/50 mix of alternative fuels in its planes, vehicles and ships within the next 10 years. Goals such as these, if backed with long-term actions, will establish the proper incentives for the energy, transportation, and agricultural industries to respond.

Although there are many variables impacting the biofuels industry, the tipping point for biofuels to gain momentum as an alternative to oil lies in a delicate balance between a number of industries and their associated interactions. The following diagram (See Figure 6) is an attempt to capture the inputs to the biofuels industry in terms of its foundation, where the industry needs to go, as well as what critical "drivers" will influence the movement of the industry. The desired

outcome is a bona fide market to supply alternative energy for transportation in lieu of petroleum products.

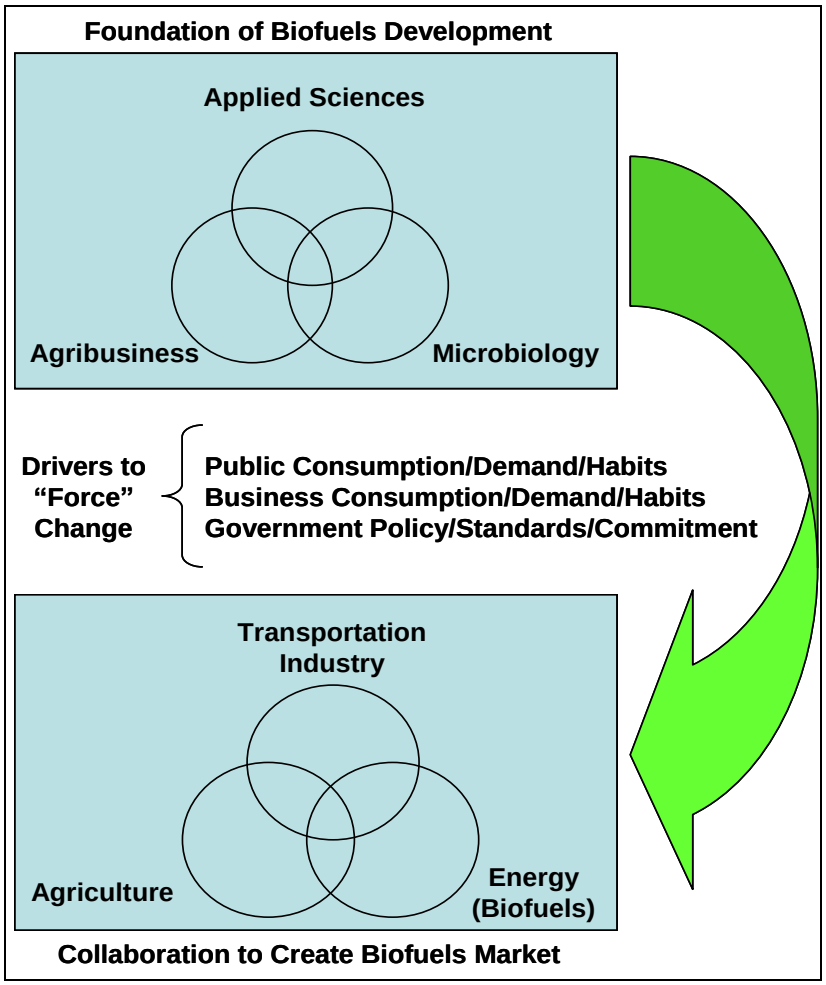

Figure 6: Biofuels from Foundation to Market

The gap between current reality and the lofty goal of promoting a substantial alternative fuel market could not be more stark. In 2006, fully 86% of America's energy consumption was provided by burning fossil fuels. Biofuels accounted for a mere 3% of that energy consumption. Government can provide a much needed catalyst to address the key challenges in creating the disruptive technology needed to realize biofuels potential. It is likely a key aspect of future U.S national security will rely on the development of energy alternatives. In the case of biofuels, the U.S. must lead the way as no other country will have the incentive to take us to the promised land of energy independence.

III. Emerging Trends

Biotechnology is a young industry but over the last three decades has already produced advancements in critical sectors such as agriculture, healthcare, and the environment. Science, however, has only just begun to delve systematically into the complex functioning of life. The

next 50 years will likely be an age of biological discovery, with emerging trends changing our lives and meriting our close attention.

Synthetic biology offers a future of game-changing possibilities in energy, medicine, national security, and environmental remediation. Synthetic biology is the design and manufacture of biological organisms -- the rational engineering of biological systems. It is a convergent and interdisciplinary field, transposing physics and chemistry to biology, and grows out of our understanding of biological systems. There are, however, two very different strategies to maximizing its societal and commercial value. A bottom-up approach follows a systems biology to assemble biological parts producing a desired effect or even a stand-alone product. This approach has limitations, as it is a struggle to organize tens of thousands of DNA pairs to achieve specialized functioning gene sequences. The opposite method is much more radical -- a top-down approach with the goal of creating new life forms. Most scientists are pursuing the bottom-up method of transplanting small, customized genetic pathways into existing genomes. Time will tell if the top-down approach can produce a game-changing breakthrough, but the logical paths to creating widespread societal and commercial value likely lie somewhere in between the vast chasm separating the bottom-up and top-down approaches.

Personalized medicine may not be as far off as the public assumes with the cost of sequencing an individual's DNA down to $1,000. Such information will permit the tailoring of treatment courses, and ultimately even pharmaceuticals themselves, to an individual's unique DNA. The sequenced genome will predict a proposed treatment's safety and efficacy before it begins. The same information will predict accurately individual predisposition to specific diseases. Beyond mere predictions, gene therapy will involve the systematic direction of genetic materials to correct defects or create desired traits. Such gene therapy could become its own industry or an adjunct field to personalized medicine. Another emerging personalized trend will be new delivery systems designed to target tumors and other localized aliments with minimal damage to surrounding healthy tissues. Finally, regenerative medicine based on stem cell research has the potential to become the ultimate form of personalized medicine.

There are clearly more aspects to emerging trends in personalized medicine than just better treatment. The field raises ethical and moral questions as rationing of treatments will become easier. Better information should allow individuals, doctors, insurance, and government to make accurate and timely care decisions. At the same time, the same information might lead to a climate where the financial cost of an individual's treatment or susceptibility to disease are openly known to government and employers and become the basis for health rationing or even discrimination.

Bioinformatics has long meant the application of statistics, databases, and computing power to the maintenance and analysis of biological information. It has become increasingly critical, as science's ability to extract information from the mapping of DNA and protein sequences has grown exponentially. Much of the emerging promise of personalized medicine will be predicated on the future capacity of bioinformatics. One of the current constraints on further advancements in many biotechnology sectors is the massive amount of data being generated. Our ability to further our understanding of biological functions and processes faces the danger of being limited by our computational ability to organize and analyze them. The

continued flood of data and growing integration of chemistry, evolutionary biology, and informatics are trends that will become more prominent. Without further theoretical, computational, and organizational progress in bioinformatics, there will be clear-cut limits on our ability to realize the full value of biotechnology. Adoption of new methods of analysis such as large-scale cloud computing might be part of the answer. A concerted push to improve our ability to handle biological data will be just as important a trend as the scientific effort to understand better life itself.

Biofuels address a clear national security need – the reduction or even elimination of our dependency on imported petroleum. Ethanol from corn and other biomass sources is already a component of the U.S. energy-sourcing matrix. These sources have not provided, however, the type of breakthrough needed to achieve even a measure of energy independence. As such, many U.S. companies are pursuing fuel-emitting algae as an avenue for creating products ranging from jet fuel to industrial inputs to unrefined petroleum to replace imported oil. There are many proven methods of producing petroleum and its related finished products from algae, but so far, none have become commercially viable. That will likely change in the near term as geopolitical events and trends raise the price of a barrel of imported oil, and the science behind algal fuels enjoys further advances. The successful commercialization of such fuels is the most strategic, realistic, and game changing of the emerging trends.

Security and Biodefense encompass many emerging trends already visible and others that will pose new challenges. The international and transparent nature of much of the scientific cooperation in biotechnology makes governmental management of some of the associated risks difficult if not impossible to manage. The danger of bioerror – the accidental release of material by a legitimate user – is just as grave a threat as bioterror, the malicious release of a harmful biological substance. Biodefense will likely increasingly emerge as a key defense industry sector for combating biological threats in military operations and for the public good. As science delves deeper into biology's complexities, it can be expected that governments' understanding of, and ability to address such dangers proactively will decrease. Only the most forward-looking of biodefense efforts will offer even the glimmer of hope of addressing an as-yet-unthought-of biological challenge, either man made or accidental. Each government will likely maintain its own regulatory process, and thus its own assessment of acceptable bioerror and bioterror risks. While many in science will continue to approach as one cohort the discoveries of the next fifty years, governments are unlikely to respond in kind. This gap will soon become even wider.

The Genie is out of the Bottle. Much as life itself forges ahead, so will our understanding of it. We will increasingly realize it will be impossible to turn back the clock on science, even if individual stakeholders might potentially wish to do so. We will increasingly inhabit a world where biotechnology is a part of every corner of our everyday lives. We will be able to control an ever-growing set of biological tools, but there will be second and third order effects we have not yet imagined. What will continue to emerge is how little we have mastered and how far we have yet to go.

OUTLOOK: THE FUTURE OF THE BIOTECHNOLOGY INDUSTRY

Future stakeholders in government, academia, and industry will need to address emerging trends. In the more immediate near term, the biotechnology industry will face a more familiar outlook – mergers and acquisitions, the need for R&D, the evolving role of government, and the increasing competition posed by a globalized economy.

Near Term: 2011-2016

The strategic outlook for the biotechnology industry to 2016 is positive, and it will likely remain in a strong growth phase. Developments herald an increasing range of industry services and products with unprecedented potential for future novel, value-creating products and services. With trends such as the aging U.S. population, mounting pressure for sustainably renewable energy to reduce a reliance on oil imports, increased global demand for food, and the vast potential of biotechnology to meet such demands, the industry will deliver a strong performance up to and beyond 2016. Forecasted annual industry growth of 9.6% totaling $146.2 billion will far outpace U.S. GDP growth to 2016. The four major factors determining the industry outlook to 2016 and beyond are the increasing role of mergers and acquisitions, investments/R&D, government influence, and the development of global markets and competitors.

Mergers and Acquisitions. In the 1980s and through much of the 1990s, big pharmaceutical companies (Big Pharma) avoided biotechnology because of the high risk of failure and cost of R&D. Big Pharma is now embracing biotechnology and outsourcing the early discovery phase of development and innovation through mergers and acquisitions, expecting that it will provide a wealth of new products that drive future growth. In the area of genetically modified crops, partnerships between large and emerging companies are increasing and the pace of commercial discoveries worldwide is estimated to increase from 30 discoveries today to over 120 by 2015.[28] Virtually every major player in the industry has been involved in at least one merger and acquisition deal in the previous five-year period. That trend is expected to continue, if not accelerate, in the years ahead as companies look to broaden product lines and expand into emerging markets where the industry growth rate is higher than in developed nations. Although reducing R&D overhead by outsourcing development risk to smaller startups is attractive to larger firms, this trend may hinder innovation as the number of larger firms consolidate and become ever more risk averse. In the five years through 2016, the number of industry operators is expected to remain nearly flat as failed companies and mergers and acquisitions negate the increased number of new entrants.

Investment and R&D. The relatively untested commercial value of much of biotechnology means that the fallout from the 2008-2009 recession will continue to influence the industry out to 2016 in two key areas. First, investment funds for start-up and small companies have become more difficult to source as venture capital investors seek companies with products of proven commercial viability. Second, many companies pared back R&D spending due to concerns about financial resources. Two-thirds of U.S. biotechnology firms reduced spending on research in 2009, and overall R&D spending was down 13% after years of double-digit increases (See Figure 7). Biotechnology is a research-driven industry over the long term, with R&D costs increasing to 22% of revenue in 2011.[29] The follow-on effects of reduced R&D spending from

2008-2010 are likely to manifest themselves in fewer novel products being brought to market in the next five years than would have been the case had R&D expenditure been maintained at higher levels. Another outcome of R&D reductions is the academic community's shifting of its scientific discovery focus from the public good to commercial profitability. Although applied science discoveries can be lucrative for individual academic institutions and their scientists, the overall decline in pure science discoveries could eventually hinder the biotechnology industry if this trend continues.

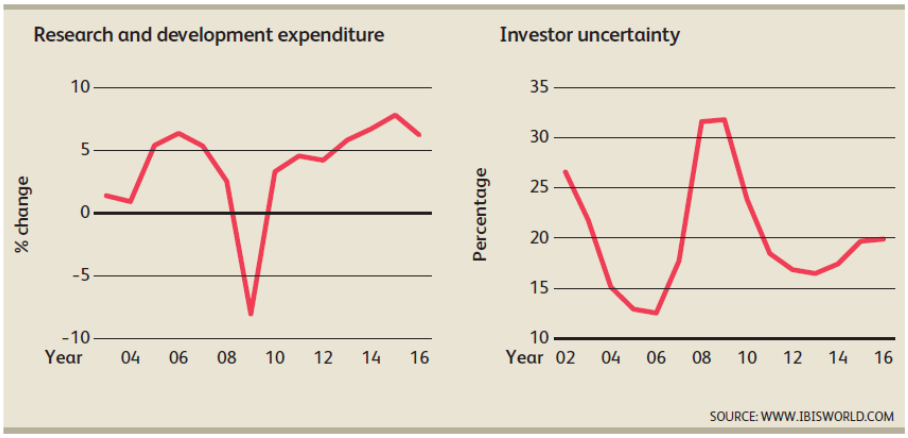

Figure 7: Forecasted R&D Expenditure and Investor Uncertainty to 2016[30]

Government Influence. As the biotechnology industry continues to mature, its growth and ultimate value will be heavily influenced by government policy and the timely application of consistent regulatory requirements. Inconsistent and prolonged approval timeframes can slow down or even derail value creation by preventing the introduction of novel products to market. This outcome can in turn reduce investor confidence and interest in products which find themselves in the earlier stages of discovery or development.

Uncertainties over the long-term political viability of the 2010 Patient Protection and Affordable Care Act and the government's ability to reduce healthcare costs will further challenge innovation in novel drug development. Attracting investors for the development of novel drugs could become increasingly difficult. A logical outcome would be for Big Pharma and investors to turn instead to the development and marketing of biosimilars.

Over the next five years to 2016, new entrants to the industry will likely become increasingly reliant upon the government for funding, the academic community for discovery and venture capitalists for survival of the development phases. With prolonged development timeframes, inconsistent application of regulations, and potential reductions in government investment and incentives, it could become increasingly difficult for small companies to develop novel products and bring them to market.

Global Markets and Competition. Looking out to 2016, biopharmaceuticals will remain the largest market in biotechnology, but other industry segments are likely to experience greater levels of growth than in the previous five years. While the U.S. is well positioned to take advantage of growing sectors and capitalize on emerging markets, many other national governments have staked at least a portion of their future economic growth on biotechnology as

a key growth engine. This Industry Study Team looked at the emerging biotechnology industry in Asia, specifically Singapore, Malaysia, Thailand, and China. Our analysis revealed four overarching themes: the importance of initial government support and the difficult transition away from it; the lack of a risk-taking attitude in some Asian cultures; the tension between economic value and societal value; and, the critical role of human capital.

Government Support. The biotechnology industry in Asia has benefited from substantial government support over the last 15 years or more. In each instance, the government views success in the biotechnology sector as a way to create enduring economic strength. As a result, government funding has facilitated the development of biotechnology sectors in very short periods of time. In general, government efforts in the Asia have taken a two-pronged approach: to create indigenous biotechnology capabilities and to encourage foreign companies to relocate their biotechnology efforts to the region. With regard to the first prong, the most significant gains in establishing such capabilities have been made in the downstream part of the value chain, specifically manufacturing and commercial applications in agriculture and aquaculture. While the ultimate desire is for global relevance in biotechnology, each has a near-term focus on national and, to a certain extent, regional applications. The difficulty each faces is in transitioning government-initiated and -funded efforts to stand-alone commercial entities. For the second prong, these governments are using attractive incentives to lure foreign businesses via tax policies and access to hundreds of millions of potential biotechnology consumers. While many foreign companies have made their way to this region based on the ease of doing business and the attractiveness of these incentives, most are unwilling to commit to significant research and development investments due to challenges in intellectual property protection and access to appropriate human capital.

Risk Taking. One of the major obstacles to the development of the biotechnology industry in Asia is the cultural aversion to risk. The discovery and commercialization of biotechnology products is by its very nature a business that involves great risk. The translation from discovery to commercial product involves the failure of many potential formulations before a successful product is realized. The U.S. biotechnology industry has been successful because of the entrepreneurial spirit embraced by its populace from the inventors who find it acceptable to fail to the venture capitalist who is willing to invest money despite great risk. The overwhelming consensus of Asian industry and government representatives was that risk aversion presented a tremendous challenge to their continued biotechnology development. Unless this aversion to risk is overcome, Singapore, Malaysia, Thailand and China will continue to serve primarily as manufacturing centers for biotechnology, not leaders in innovation.

Economic versus Societal Value. A third factor noticeable throughout Asia's efforts to develop biotechnology is the tension between the pursuit of commercial value and the need to promote social well being. The ultimate emphasis on social harmony is a key reason why many governments find it difficult to extradite themselves from financial support of firms. It is a simple reality that many biotechnology firms in Asia either have the national government as the majority stakeholder or could only exist thanks to major tax incentives. Many government-supported firms certainly add economic value in terms of national wealth creation but governments also tend to spend significant resources to support most of them – often for decades – until they become economically viable on their own. What society does immediately obtain

from these firms, regardless of the net financial drag on government, are clear societal benefits. These benefits range from employment to the development of human capital to a national focus on key resources. There appears to be no easy solution to this tension as government support was often the key to the creation of individual firms and the national biotechnology sector itself. It would seem many Asian governments have decided that the larger benefits their societies derive from government-supported firms outweigh any demands such support place on government coffers.

Need for Human Capital. In the area of human capital, the future might well bring an era of fierce global competition for the technically skilled work force. The need in Asia's biotechnology industry for deeper and broader human capital can be keenly felt. There is no shortcut to developing human capital, and there was ample evidence in at least some countries of a credible, long-term commitment to creating it. In the meantime, the U.S is positioned to play a key role in meeting the demands of developing countries for science and technology knowledge through our university education system. Further adapting U.S. immigration laws to provide incentives to highly skilled foreigners attending U.S educational institutions to remain in the U.S. in the biotechnology sector could further enhance our research capacity and supplement the biotechnology industry base with the next generation of high-caliber scientists.

Long Term: Beyond 2016

Five years out might not seem like the long term but the rapidly changing technological possibilities of biotechnology coupled with the exponential nature of the demands for food, fuel, and healthcare mean that anything beyond The world's population is projected to reach 9.1 billion by the middle of this century[31] This increase will continue to tax our planet's natural resources and place demands on governments to provide for their people. Aging populations in the world's most developed countries bring with them new demands for safe, affordable, and effective healthcare. As genome mapping and personalized therapeutics progress, the bioinformatics sector of the biotechnology industry will significantly expand to handle the concomitant enormous volumes of information. Additionally, stem cell-based technology and biotechnology therapeutics will overtake current drug development technology in pharmaceuticals, possibly resulting in increasing ethical concerns over the expansion of bio-based life science solutions. Increasingly complicated ethical dimensions, long develop-to-market timeframes, and enormous venture capital risk will increase the outsourcing of U.S.-owned R&D to lower cost nations with emerging technical capacity.

With the global population expanding, the requirements for sustainable and renewable food and energy sources become greater priorities. Environmental concerns and finite fossil fuel resources will demand energy alternatives, resulting in a future increase in global biofuel production. This transition is inextricably linked to global fuel prices and future transportation habits. The industry will likely undergo a shift from the current domination of the health care sector (65% of market share in 2011) to the emergence of dominant agri-energy sector.

According to the United Nations Food and Agriculture Organization, food demands will require a 70 percent increase in overall agricultural production, primarily in the developing world.[32] A growing global middle class, with its increased meat consumption, longer life

expectancy and greater age-related health care demands will drive governments around the world to seek alternate solutions to meet social carrying capacities. Added to that, acceptance of genetically engineered products by the developing world, driven by population growth, climate distress and resource scarcity will trigger global growth for the agribusiness sector and offer an increasing export share for the U.S. biotechnology industry.

Looking even further ahead, the disruptive promise of synthetic biology -- the design and manufacture of biological organisms -- is a future full of game changers and major tactical upgrades: cheap petroleum from algae, inexpensive food production, individualized medicine based on gene therapy, new medicine for drug-resistant diseases, and bioremediation of environmental disasters. The core of the promise of synthetic biology is the practical. Its answers speak to commercially viable solutions related to concrete needs.[33] Its promises enhance national security, while also producing commercial value. Whether in health, food production, the environment, security or energy, the field holds the promise to transform our lives and take the biotechnology industry in every direction imaginable.

RECOMMENDATIONS

Many economic sectors expand and contract due to market forces, but the biotechnology industry is more sensitive than most to external influences, such as politics and public opinion. This makes the biotechnology industry's ability to create economic and societal value subject to additional influences than its own structure, conduct, and performance. Political imperatives such as national interests, national security, global challenges, and public debate of controversial technologies often drive policies and regulations. In light of this complex operating environment, the following recommendations represent opportunities to balance government's role, industry vulnerabilities, academic advances, and market forces to assure a positive pathway for the U.S. biotechnology industry to realize its full economic and societal value.

Recommendation #1: Government expertise must keep pace with evolving technology. Biotechnology continues to develop at such a rapid pace, it is a challenge for government regulation and expertise to keep pace. Government should consider innovative approaches to ensure the relevant expertise exists both in the regulatory and policy frameworks to protect both the public good and to promote the maximum value creation by industry. Whether pursuing an "eyes on, hands off" approach to new technologies so as not to stifle innovation while maintaining the prerogative of governance or creating a more flexible arrangement between industry and regulators, an active government role in the Triple Helix is paramount.

Recommendation #2: Government must implement more consistent application of regulatory policy. Based on overwhelming feedback from varied and extensive field visits, industry highlights the "inconsistency" in regulatory policy enforcement and interpretation. Industry cites the inconsistency in reviews by FDA, APHIS, and the EPA as the single greatest threat to the industry's ability to advance products to market in a timely manner which in turn represents a barrier to innovation. Additionally, regulatory agencies often lack appropriately trained and skilled personnel to facilitate the approval process. As a result, the engagement of experts from within academia as consultants to review submissions on a part-time basis could provide an injection of specialist resources currently lacking in regulatory agencies. Conducting

quarterly review boards for two weeks, as an example, could ensure minimal disruption to parent academic institutions. Using participation and availability of personnel for these boards could be used as a metric to determine ongoing R&D funding.

Recommendation #3: Rebalance government R&D funding. The government should consider reallocating R&D funding, especially in biopharmaceuticals, from early discovery phases to early clinical trials to help smaller companies and academia overcome the "valley of death". This could serve as a bridging effort to promote more products to a phase where venture capitalists are most willing to invest. The end result could be more beneficial products to market.

Recommendation #4: Implement government policies to drive open and transparent information sharing within academia. Current funding to academic institutions is often duplicative and inefficient. Mandating the publishing of results, in particular failures, to secure government R&D funding provides an avenue to address the issue. As academia openly shares information regarding research "dead ends," more effective and rapid development of viable products would be enabled by avoiding duplicative and doomed research efforts.

Recommendation #5: Implement government funding and support policies to encourage academia to develop innovative human capital incubators. Incubators at academic institutions allow talented young biotechnologists to access funding and workspace within the academic environment to pursue promising ideas and generate otherwise unachievable start-up companies. Subsequent shared intellectual property and commercial profit could provide a potential return on investment for government R&D funding. This will allow an additional focus on technology transfer and the translation of innovative ideas to market that may not be substantially profitable, but nonetheless useful to enhancing the public good.

Recommendation #6: Implement government immigration policy which enables and incentivizes industry to utilize global human capital. While the development of domestic science, technology, engineering and math focused human capital remains an issue for government consideration across all industries, biotechnology human resource experts highlight a potential resource to bridge the gap. Sources within industry suggest an overwhelming number of international applicants exist to fill vacancies, however current U.S. immigration and naturalization policies are not conducive to retaining them for the medium to long term.

Recommendation #7: Government policy should foster energy, environment and food technologies to address emerging global challenges highlighted in the national security strategy. This recommendation reflects two key initiatives. First, government incentives for biotechnology companies should be equivalent to overseas competitors in order to encourage firms to remain in the U.S. Second, the government should consider incentives for companies investing in "green technologies" in order to provide a pathway for innovation and growth. Implementing taxation policies which discourage continued reliance on fossil fuels could help generate the revenue to fund the green incentives. Such policies address global responsibilities identified in the national security strategy and foster emerging biotechnology sectors.

CONCLUSION

U.S. biotechnology still finds itself in the growth phase of the industry life cycle. It is healthy and vibrant as a sector and is well positioned to address a broad spectrum of unmet needs found in megatrends facing our nation and the globe. Additionally, the industry is growing and holds significant importance for U.S. National Security in its potential for economic growth and contributions to global stability by addressing food and energy challenges. In addition, biotechnology is a key defense industry for combating biological threats in military operations and for the public good. Presently, the U.S. holds a comparative and competitive advantage in the global biotechnology industry, with 43% of the global market revenue, projected annual growth rates of 9.6%, and more novel products coming to market than any other nation.[34] The U.S. biotechnology industry remains well-positioned to retain its global competitive and comparative advantage in the near term, provided the government retains a robust effort to promote innovation and speed the translation of concepts to commercial products.[35]

After a period of funding challenges due in large part to the global recession, the U.S. biotechnology industry appears poised to make solid gains in the next five years in genomics, bio-fuels, and bioinformatics. The advances in genomics should lead to personalized medicine and a new model reducing side effects and improving the value of therapeutics. The need for U.S. energy independence will continue to drive bio-fuel development, and a burgeoning world population will increase the need for higher yield, pest-resistant crops promised by bio-agriculture. The world's fundamental need for the type of disruptive innovation which only an industry such as biotechnology can provide makes its future bright. The unique "triple alliance" between academia, government and industry will continue to be the center of gravity for the U.S. biotechnology industry. It exists fully formed in the U.S. and provides a significant competitive advantage in an increasingly globalized industry. We must do all we can to maintain that alliance and to strengthen it further to remain the world biotechnology leader for years to come.

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[7] Ibid., p4

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