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BIOTECHNOLOGY 2014

ABSTRACT: The Biotechnology Industry Study Group analyzed the $262 billion global biotech industry, which includes four broad segments: human health technologies, agriculture and aquaculture technologies, industrial and environmental remediation technologies, and biodefense. In our analysis, we put a particular emphasis on the agricultural segment given that new research shows that food insecurity is a growing source of conflict around the globe. Although the biotechnology industry is still in its growth stage, it is being challenged by cuts to U.S. Government programs that support the industry at all points on the value chain, scarce investment capital, falling demand for biofuels, unresolved safety and ethical issues, undefined regulatory pathways for promising new products, and a lack of biotech literacy amongst potential consumers. While price competition between major firms should encourage farmers in developing countries to continue to adopt existing biotechnologies that increase crop yields, there are high barriers to entry. This raises concerns that this industry is losing its capacity to produce the new, disruptive technologies that will be needed to keep pace with climate change and projected demographic growth. To mitigate this possibility, we offer eight recommendations to strengthen the U.S. agricultural biotech sector and, ultimately, U.S. national security.

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PLACES VISTED

Domestic:

California
Arcadia BioSciences (Davis)
Ajinomoto Althea (San Diego)
BayBio Northern California's Life Science Association (South San Francisco)
BIOCOM Regional Life Science Association (San Diego)
Bio-Rad (Hercules)
PaxVax (San Diego)
Sandia National Laboratories (Livermore)
SRI International (Menlo Park)
University of California QB3 California Institute for Quantitative BioSciences (South San Francisco)

Maryland
Center for Biosecurity of the University of Pittsburgh Medical Center (Baltimore)
Edgewood Chemical Biological Center (Aberdeen Proving Ground)
Montgomery College Biotechnology Laboratory Research Program (Rockville)
National Institutes of Health (Bethesda)
University of Maryland Institute of Marine Biotechnology (Baltimore)
U.S. Food and Drug Administration (Silver Spring)

Massachusetts
Amgen (Cambridge)
Broad Institute of MIT & Harvard (Cambridge)
Charles River Laboratories (Wilmington)
Boston Children's Hospital (Boston)
Draper Laboratory (Cambridge)
Harvard Stem Cell Research Institute (Boston
Massachusetts Biotechnology Council (Cambridge)

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Biotechnology Industry Organization (BIO)

International:

Republic of Korea
Celltrion (Incheon)
CJ Pharma Osong Plant (Osong)
Joint U.S. Military Affairs Group, Korea, U.S. Forces Korea
The Embassy of the United States Seoul
Korean Biotechnology Industry Organization (Gyeonggi-do)
Korea Health Industry Development Institute (Chung Buk)
LG Life Science Daejon R&D Center (Daejon)

INTRODUCTION

Technological innovation is a significant driver of economic growth, and the economic activity that is fueled by research and innovation in the biological sciences is a large and rapidly growing segment of the world economy. Promoting this "bioeconomy" is a priority for the Obama Administration, as well as the majority of our Allies and partners, because of its tremendous potential to sustain economic growth and to provide substantial public benefits. Decades of life-sciences research are creating increasingly powerful tools to obtain and use biological data that foreshadow major advances in the areas of health, biological-based energy production, agriculture, manufacturing, and environmental clean-up. These new technologies promise longer lives, reduced dependence on oil, and new tools to respond to environmental challenges.

This report, prepared for the Dwight D. Eisenhower School for National Security and Resource Strategy by its Class of 2014 Biotechnology Industry Study Group, analyzes the health of the global biotechnology industry. In conducting our assessment, we placed particular emphasis on the challenges affecting the industry's agricultural biotechnology segment, given the growing threat of food insecurity as a source of conflict. In addition to reviewing the available secondary data from a variety of academic, government, and news sources, our findings are based on interviews conducted between January-April 2014 in Washington D.C., Boston, San Diego, San Francisco/Silicon Valley, Davis, and Seoul, with representatives from biotech firms, academic institutions, non-profits and government organizations that fund, research, and commercialize biotechnologies or that support the federal structures by which they are regulated.

Currently, the United States is leading the world in biotechnological research, and the sales of biotech products and technologies, due to the development of three foundational technologies: genetic engineering, DNA sequencing, and automated manipulations of biomolecules like proteins.[1] While the potential of these breakthrough technologies is not exhausted, continued growth will depend on developing emerging technologies, such as synthetic biology (the direct engineering of microbes and plants), proteomics (the large-scale study and manipulation of proteins in an organism), and bioinformatics (computational tools for expanding the use of biological and related data). It will also depend on the development of new ones. In a knowledge-based industry, funding for basic scientific research is as critical as investing in translating the science into products. However, our group found that the current levels of private and public investment in early-stage research may be inadequate to maintain the innovative capacity of the industry.

More critically, we found biotech investment capital to be highly concentrated in the segment of the industry dedicated to human health. In contrast, early stage research in the agricultural biotech sector has contracted over the last ten years. This raises concerns that we are approaching an inflection point where additional advances in biological research -- including enhanced crop yields, better nutritional content and less pesticide use -- will fail to keep pace with projected environmental and demographic challenges. This paper examines the challenges involved in reversing this trend, including the debate surrounding the production and trade of genetically modified (GM) food, and offers policy recommendations to strengthen the U.S. agricultural biotech sector and, ultimately, U.S. national security.

THE FOOD INSECURITY-CONFLICT-BIOTECHNOLOGY NEXUS

Last June, Secretary of State John Kerry awarded three biotechnology scientists the 2013 World Food Prize, with the following observation about food insecurity:

> It can actually feed into terrorism. It feeds into failed states. It feeds into all of the challenges that we face in terms of building order and creating stability on this planet…the struggle for food is, in the end, a struggle for life itself.[2]

While there is substantial empirical evidence that conflict causes food insecurity, the case that food insecurity can cause conflict has been more difficult to make, partly due to the fact that there are so many underlying causes of food insecurity. However, in 2008, rapid increases in global prices for major grains helped to trigger outbreaks of civil unrest in more than 40 countries, prompting scholars to pay increased attention to the potential influence of food availability on social and political instability.[3] A new body of research on the dynamics of conflict is now underway, and the case studies that are emerging are helping to build consensus within the national security community that there are several ways in which food insecurity could spark future conflict.[4]

Future Food Requirements

Over the last 15 years, the population of the world has grown by one billion to reach 7.2 billion.[5] One in eight people in the world (a total of 842 million) are chronically undernourished.[6] According to the most recent United Nations demographic projections, the world's population is likely to reach 9.6 billion by 2050, 34 percent higher than today.[7] Experts predict that 88 percent of this population increase will occur in the developing countries of Africa, Asia, and Latin and South America, which are the very regions that have struggled most with malnourishment over the past century.[8]

In addition, urbanization is expected to accelerate; by 2050, over 70 percent of the world is projected to live in urban areas, compared to 49 percent today.[9] As cities and urban areas expand their footprints, they leave less land available for agricultural use and require more food to feed their populations. Urban populations' diets also change.[10] The United Nations' Food and Agricultural Organization (FAO) noted that due to economic growth and urbanization of the 1960s "the consumption of milk per person has almost doubled in developing countries, meat and fish consumption has tripled, and egg consumption has increased by a factor of five".[11]

Finally, crops are increasingly being used for bio-energy and other industrial purposes. Due to the mandated use of biofuel, demand for "agricultural feedstock – including corn, soy, and sugar cane – as inputs for the production of biofuels is projected to grow".[12] By 2020, biofuels are projected to consume 13 percent of global coarse grain production, 15 percent of vegetable oil production and 30 percent of sugar cane production.[13]

In order to feed the growing urban population and meet the increased demand from bio-based energy and industry, the FAO projects that food production must increase by 70 percent: "Annual cereal production will need to rise to about 3 billion tons from 2.1 billion today and annual meat production will need to rise by over 200 million tons to reach 470 million tons."[14] A significant amount of this increase could be met by reducing spoilage, but not all of it. According to this same FAO report, "80 percent of the necessary production increases will need to come from increases in yields and cropping intensity and only 20 percent from expansion of arable land"[15]. Moreover, modern agriculture is dependent on the application of fertilizers containing phosphorus, nitrogen and potassium to sustain crop yields. Phosphorus is derived from phosphate rock, which is a non-renewable resource that some experts predict will be depleted within 50 years.[16]

Additional Emerging Threats

Aside from demographics and competition with other biotech-based industries, climate change and water table depletion are intensifying the risk of future food insecurity.

Climate Change. Higher growing season temperatures have dramatic impacts on agricultural productivity since they interfere with pollination and reduce photosynthesis.[17] The International Rice Research Institute in the Philippines recently determined that a temperature increase of just one degree Celsius during the growing season lowers wheat, rice, and corn yields by 10 percent.[18] Some experts predict that the impact will be greater at higher latitudes and in continental interiors than in equatorial and coastal regions.[19] But a recent study that uses observational data and output from 23 global climate models concludes that there is 90 percent probability that rising temperatures in the tropics and subtropics will also exceed the most extreme seasonal temperatures recorded between 1900 and 2006 by the end of the century.[20]

Aquifer Depletion. Although the development of technologies to tap underground water sources has expanded world food production, it has also led to significant drops in global water tables, which are starting to threaten grain producers in China, India, and the United States. Together these three countries currently produce half of the world's grain.[21]

The Agroterrorism Threat. Biological weapons have long been a part of arms portfolios, however technology is increasing the persistency, potency, and availability of biological agents. In the wake of the September 11 and anthrax attacks in 2001, the U.S. Department of Agriculture (USDA) and Department of Homeland Security (DHS) expanded education and surveillance programs to detect the intentional release of pathogens directed against the food and water supply.[22] Experts currently differ in their assessment of the threat posed by potential actors seeking to employ such weapons on a large scale, but they generally believe it is sufficient to command the attention of national security planners and recommend that we develop more robust prevention plans.[23]

Hungry People Are Angry People

These trends are alarming in light of a growing body of research into the connection between food and political stability mentioned above.[24] Recent case studies suggest there are two ways that food insecurity could spark future conflict:

Sudden Food Price Rises Trigger Conflict. Food prices can rise rapidly in response to shifts in global markets, local shortfalls in supply that are not compensated by trade, or deliberate changes in policies, especially those that remove subsidies or price controls. For example, in 2010, Russia experienced a drought where global grain production was reduced by one percent but resulted in a 60-80 percent price increase.[25] In 2007 and 2008, protests against extraordinary increases in the price of rice (and to a lesser extent the prices of wheat and corn) led to outbreaks of civil unrest in 48 countries.[26] Researchers at the New England Complex Systems Institute in Cambridge have also recently concluded that it was highly likely that high food prices in 2011 were a precipitating condition for the Arab Spring.[27]

Competition for Food Production Resources Catalyze Conflict. Struggles to control access to water and land have long been identified as sources of communal conflicts, such as recent violent conflicts between permanent or semi-permanent militias in Kenya, Nigeria, the Sudan and Uganda.[28] Interviews with demobilized combatants in Sierra Leone and Liberia provide some evidence that poorly educated rural youth joined those conflicts to increase their chances of securing agricultural land through predation or the spoils of conflict.[29] Recent studies suggest that large-scale land acquisitions have incited protests, riots, coups, and other conflict in Mali and Madagascar.[30] As foreign governments and corporations lease and purchase large tracts of arable land across the globe, the potential for food-related resource conflicts to spark conflict at the national level may increase. Indeed, we found that 20 of the 33 "hot spots" recently identified by the Council on Foreign Relations can be tied to food security issues.[31]

The Challenge for the Biotechnology Industry

If food insecurity can be a threat multiplier for conflict, many leading researchers in conflict prevention are starting to surmise that improving food security can also reduce tensions and create more stable environments.[32] Recent analysis by the FAO suggests this is a challenge for the biotech industry:

> Globally the rate of growth in yields of the major cereal crops has been steadily declining, it dropped from 3.2 percent per year in 1960 to 1.5 percent in 2000. The challenge for technology is to reverse this decline, since a continuous linear increase in yields at a global level following the pattern established over the past five decades will not be sufficient to meet food needs.[33]

The following sections of this report assess the industry's capacity to meet this challenge. After providing an overview of the industry, and an assessment of the competitive forces and policies that are currently shaping it, we identify the emerging technologies that could potentially stem water and food insecurity. Finally, we assess the industry's future capacity to develop innovative biotech products, and offer recommendations that would help strengthen it.

THE BIOTECHNOLOGY INDUSTRY DEFINED

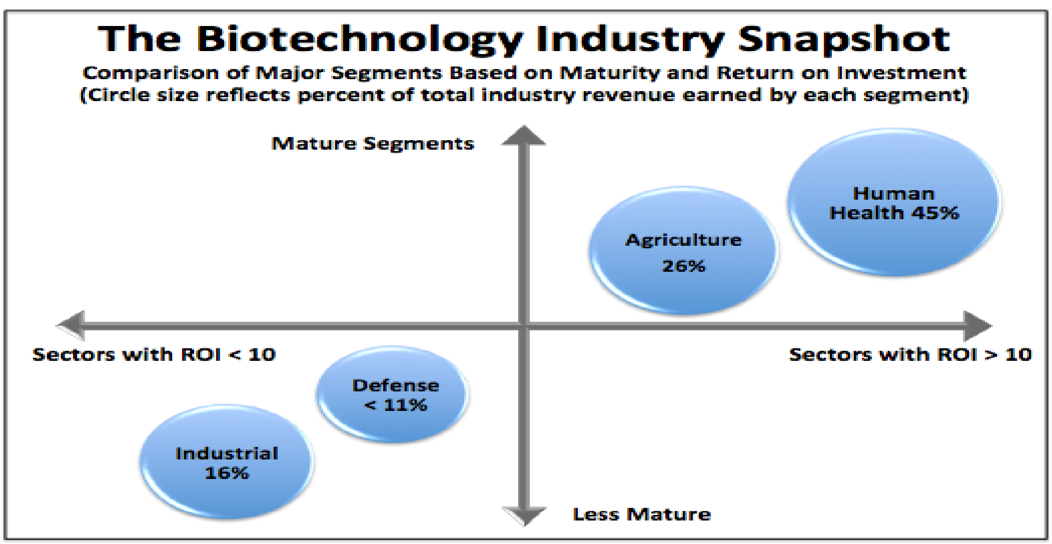
The reporting system used in North America to capture economic activity does not neatly segment the economy in a way that captures all of the research, development, production, and employment involved in the creation of biological processes and products. In 2006, a National

Biotechnology Advisory Committee met to discuss this problem and suggested that the biotechnology industry could best be defined to include 23 different North American Industrial Classification System (NAICS) industry codes or subsectors that use biotechnologies. These include manufacturers and service providers that harness cellular or bio molecular processes to produce chemicals and food, as well as medical services. They also include firms that perform contract research for these producers and that manufacture the research and biological equipment they use to develop and commercialize their products.[34] In 2012, the U.S. Biotechnology Industry Association (BIO) identified an additional four biotech-based NAICS industries in its biennial assessment of the growth of the biotech industry.[35]

What links these 27 industries is that they make use of the scientific developments that have transformed the practice and potential of biological research over the past thirty years, including genetic engineering and DNA sequencing.[36] In other words, the biotech industry is defined by a set of enabling technologies that rely on living things to make or provide services that are used in a wide range of economic activities, as opposed to a set of products, like aircraft systems. As a result, many international organizations, as well as the Obama Administration, prefer to use the term "bioeconomy" rather than biotechnology industry.[37]

Snapshot of the Major Segments

For the purposes of this report, the Biotechnology Industry Study Group has defined the biotechnology industry broadly, to include four different segments that produce products and provide services related to medical care, agriculture and aquaculture, industrial production and environmental remediation processes, and defense. A relative comparison of the size of these segments, based on their maturity and profitability, is shown in the figure below.[38]



Human Health Technologies. The vast majority of companies in the biotech industry research and develop medical products and services. Currently, this segment generates about 45 percent of total industry revenue.[39] Firms in this sector compete in three distinct markets: 1) biopharmaceuticals, also known as biologics or large molecules, which are medicinal products created through biological processes (rather than chemical synthesis) such as vaccines developed through recombinant DNA techniques and genetic therapies that are also referred to as therapeutics; 2) diagnostics which test for genes that indicate specific diseases and that allow for more accurate targeting of therapeutic treatments and medical devices and 3) biomedical devices. Of these three, biopharmaceuticals generate the most revenue ($54B in the United States in 2013).[40] While the diagnostics area is in the early stages of development the falling cost of genome sequencing promises to increase demand for personalized medicine.

Agriculture and Aquaculture Technologies. Firms in this segment compete in four distinct markets (crop production, animal health, animal breeding, and marine and microbial production) and make up the second largest segment in terms of global industry revenue (25.8 percent in 2013).[41] This segment is built on recent innovations that have enabled scientists to select specific genes from plants or animals and introduce them into other organisms, a process known as genetic engineering. This creates plants and animals with productivity-enhancing traits such as herbicide resistance or resistance to pests, viruses, or fungi. New biotech crops are also being developed to survive extreme conditions, such as drought, and that combine or "stack" several different enhancements in one seed. In livestock production, biotech products are used to improve farm animal breeding by identifying disease-resistant animals with genetic mapping. They are also used to develop animals with better growth and muscle mass. Biotech applications related to animal health are largely the same as in human health, including applying advances in genetics and molecular biology to create new therapeutic products and diagnostic tools for veterinarians. Companies involved in the marine and terrestrial microbial product line primarily investigate how those organisms adapt to extreme conditions such as high pressure or total darkness to apply them in manufacturing processes like protein synthesis.

Industrial and Environmental Remediation Technologies. This segment has grown rapidly over the last five years and now accounts for about 16.5 percent of total industry revenue.[42] Firms in this market produce biologically-created fuels and oils, as well as enzymes and other chemicals, used in a variety of manufacturing processes including those related to energy, textiles, pulp, paper, and minerals as well as oils used for cooking and food preservation. These fuels tend to have enhancements that make them more efficient than conventional oils. The environmental remediation and natural resource recovery firms in this segment manipulate enzymes and microbes so that they can be used in environmental cleanup.

Biodefense. A small number of firms in this sector are using techniques similar to those employed in the other three segments to develop products to detect, treat, and remediate both naturally occurring and man-made biological threats.

INDUSTRY STRUCTURE AND CURRENT PERFORMANCE

Because the biotechnology industry is a knowledge-based industry that depends on innovation, the definition of a success in this industry is, in the simplest terms, the ability of firms to turn science into products. Borrowing from the business management concept of the "value chain" popularized by Michael Porter, the two main activities that firms carry out to increase the value of a biotech product are: 1) basic scientific research, and 2) the translation of that research into products.[43] Although the cost of performing these activities is generally much higher than in other industries, the mechanisms used to fund them are dramatically different in the industry's four different segments. For example, in some segments there are comparatively few firms financially capable of operating along the whole of the value chain. In addition to having different ratios of firms dedicated to either research, development, or both, the economic incentives that drive the behavior of firms differs in the four segments, due to their varying customers, suppliers and regulatory frameworks. In spite of these differences, the following section provides an overview of some critical challenges and opportunities that are shared by all four segments. We then provide a more detailed look at the economic forces that are shaping the agricultural segment and assess its future outlook.

Trends Shaping the Global Biotech Industry

Taken as a whole, the global biotech industry is still in its growth phase. Most industry analysts expect all four segments to continue to grow through 2018, due to continuous technological advancements, the rapid growth of emerging markets for biotech products, and the fact that the industry's two largest markets (healthcare and food) are largely resistant to economic downturns.[44] Industry revenue grew at an average annual rate of 11 percent over the last five years to $262 billion in 2013. One study projects that it will continue to grow at an annual rate of 9.2 percent over the next five years to reach $407 billion in annual revenue in 2019.[45]

As noted above, a defining feature of the industry is its wide range of firms, including many small companies that focus on researching new technologies and operate primarily with venture capital, grants, and collaborative agreements because they have no product revenue. There are also a few giant pharmaceutical, chemical, and agricultural firms that are diversified companies with in-house research facilities and well-established production, commercialization, and distribution processes. Additionally, there are a number of firms that support them by manufacturing equipment and performing contracted research. According to the Organization for Economic Cooperation and Development's 2012 Key Biotechnology Indicators Report, the majority of these firms have fewer than 50 employees, ranging from 44 percent in Japan to 91 percent in New Zealand.[46]

With the exception of its agricultural segment, this industry has a low level of concentration. However, a recent upsurge in mergers and acquisitions driven by larger firms buying out smaller firms to acquire successful research for commercial-ready technologies, combined with the slowing rate of new entrants, is changing this picture. Some analysts project the rate of new firms entering the industry will slow to an annual rate of only 1.4 percent over the next five years. In other words, they project that there will be 8,033 biotech firms worldwide in 2019.[47]

This industry currently displays a medium level of geographic concentration, with the vast amount of revenue generated in the United States. In 2013, the U.S. biotechnology industry, comprised of more than 1800 firms, generated $93 billion in revenue or 38 percent of global revenue.[48] This accounted for approximately 0.55 percent of U.S. GDP in 2013, including $6.9 billion in exports.[49] Over 206,000 people are directly employed in the biosciences with an additional estimated 1.4 million employed in related industries in the United States.[50]
Although the biotechnology industry in Europe is also well developed, it trails the United States because it is more fragmented and has less long-term investment. Biotechnology is growing rapidly in emerging markets, particularly in the Asia-Pacific region, where China, Japan, South

Korea, Taiwan, and Singapore are investing significant amounts of capital to gain a strong foothold in the industry.[51] For example, in South Korea, the government provides its biotech industry with 2.58 trillion won (approximately $2.5B) in annual subsidies.[52] In addition, some governments, such as Brazil, are developing and directly marketing new GM seeds.[53] Thus, the structure of some biotech segments may be changing to include more state-run firms.

One of the primary drivers behind the industry's recent growth has been the increase in biotech products, particularly in the healthcare and agricultural segments. Over the past five years, revenue growth has greatly exceeded growth in the number of firms, employees and wages, which suggests that more companies are reaching the product commercialization stage. Currently, there are more than 250 biotechnology health care products and vaccines available to patients. In addition, more than 13.3 million farmers around the world use GM crops and more than 50 bio-refineries are being built across North America to test and refine technologies to produce biofuels and chemicals from renewable biomass.[54] Additionally, the falling cost of some technologies is opening up new product lines. For example, inexpensive DNA sequencing, which experts predict will fall to $1000 this year, connected to new data processing technology, is also creating novel products and services. Despite this trend, it is important to note that the vast majority of biotech companies still have not turned a profit, and are operating on the future promise that they will be able to sell their discoveries to larger firms to commercialize.

Another source of industry strength is the high rate of strategic collaboration.[55] Like other knowledge-based industries, firms regularly partner with each other, as well as with academic institutions, non-profits and government research organizations. All four of the major industry segments are dependent on this so-called "triple helix" of government, academia, and industry. U.S. and other foreign governments not only provided the regulatory framework used to test and approve new products, but supplied about eleven percent of the funding firms used to conduct their research in 2013.[56] Firms in this industry are increasingly seeking out collaborative research partnerships with universities and non-profits, such as the Wellcome Trust and Bill and Melinda Gates Foundation. The advantages of doing so include no capital outlay, low-cost labor, and access to new intellectual property. The industry's reliance on these collaborations also explains why most firms operate in geographic clusters anchored by major research institutions. Virtually all of the firms that the Biotechnology Industry Study Group visited were located in the three largest U.S. clusters: San Francisco, Boston, and San Diego.

Key Challenges

Although the biotechnology industry has great potential for continued growth, it is also facing a number of challenges. The White House identified many of these in its 2012 *National Bioeconomy Blueprint*, which aims to establish the conditions for the U.S. to become a biotech-based economy.[57] Our Industry Study Group identified six of greatest concern to the firms, research institutes, and industry organizations that we met with between January and April:

Drop in U.S. Public Funding Affects Whole Value Chain. The greatest concern harbored by the industry is the drop in U.S. public funding that resulted from the Budget Control Act of 2011's across-the-board spending cuts and the increased uncertainty over future funding created by the October 2013 government shutdown. Historically, the United States has had the largest commitment to basic research in the biological sciences worldwide. In 2013, U.S. research and development (R&D) funding for the life sciences, 85 percent of which is devoted to biopharmaceuticals, accounted for 46 percent of global R&D spending.[58] Because future innovation in this industry rests on processes that are still not well understood, stable support for federally-funded research laboratories and research grants has been a source of industry strength, particularly in economic downturns when private capital is scarce.

The industry also relies on tax credits that incentivize investment, small business loans that supply seed funding for new firms, efficient regulatory mechanisms, and policies that promote science, technology, engineering, and math education (STEM) to maintain its workforce. In California, for example, 767 biotechnology companies received more than $281 million in federal research grants under the Therapeutics Discovery Project initiative in 2010.[59] The inability of the Federal Government to maintain these programs directly impacted the rate by which new biopharmaceutical products received regulatory reviews in 2013, and threatens the ability of the United States to maintain its position as the world leader in biotechnology innovation. In contrast, emerging economies, such as China and India, are increasing public support for their biotech industries.[60]

Low Return on Investment (ROI) Limits Access to Capital. Attracting private funding is also becoming more difficult in the United States and in Europe. Current growth in the industry is largely the result of investment that was undertaken in the 1990s, given that the average lead-time between the discovery of a biotechnology and its commercialization is typically 10 to 15 years. Analysts are increasingly concerned that future investment will fail to reach these past levels. According to Battelle and R&D Magazine's 2014 Report on Global R&D, private industry has been the source of 70 percent of research and development investment in the U.S. life sciences, which is heavily intertwined with the biotech industry, in recent years.[61] However, that figure is now falling. The 2008 recession shattered investor confidence, making the prospect of raising funds through initial public offerings (IPOs) far more difficult. While there was a resurgence in biotech IPOs in 2013, venture capital investors have largely moved out of early stage research to less risky upstream product development.[62]

Most analysts believe the root cause is the dismal return they make on biotech investment. The attrition rate for new discoveries is high: only 11 percent of new biological compounds that enter clinical testing are eventually approved, and those that ultimately make it to market have to gross enough revenue to cover the investments made for the other 89 percent that failed at the clinical testing stage.[63] When the failures are added to the ledger, bringing a new drug to market costs $1.2 billion in the United States.[64] Developing an agricultural crop with a genetically-modified trait in the U.S. costs $136 million and takes an average of 10-15 years.[65] One reason the failure rate is so high is that many biological processes that underpin new products are still not well understood. As a result, many biotech firms study the same basic biological processes in the hopes of being the first to patent a new discovery, leading to wasteful duplication of effort.

The industry is trying to reduce this inefficiency by embracing "precompetitive collaborations," where rival firms pool proprietary clinical trial data and resources to jointly tackle research issues that no one firm can solve alone. In agriculture, this has led to increased sharing of genetic information on potential crop characteristics. In the health sector, these collaborations are having significant impacts in clinical-trial design and the discovery of genetic traits or biomarkers. Combined industrial R&D between rival firms is also increasing, despite the major challenge involved in developing effective communication networks across companies.[66]

Falling Demand for Biofuels. Another challenge is the falling demand for biofuels. Last year, rising natural gas and oil output in the U.S. led to the first drop in global biofuels production since 2000.[67] At an April 29 meeting, representatives from the U.S. Biotechnology Industry Organization (BIO) predicted that falling conventional fuel prices would generate calls to repeal or amend legislation requiring the use of renewable energy, which has helped to create the market for biofuels. According to BIO, these efforts also threaten the effort to develop second-generation biofuels.[68]

Unresolved Safety and Ethical Issues. While the medical applications of biotechnology are increasingly being accepted by the population, its use in improving crop yields is still contentious. Critics of the technology argue that GM foods have uncertain long-term impacts on public health and the environment. These concerns have led to regulatory barriers that are restricting the trade of some biotech products.[69] The modification of biological organisms, as well as the construction and use of organisms not found in nature, also carry potential security and environmental risks if misapplied, raising issues of responsible conduct.[70] The development of "personalized medicine," spurred by recent advances that combine information technologies with biotech, also raises new concerns over data privacy and ownership. Furthermore, Brazil has recently reignited international debate over "terminator" seed technology, which modifies seed to be sterile and requires crop farmers to purchase it on an annual basis. Its Parliament is debating authorizing the use of the technology to produce pulp for its paper industry. If passed, it could collapse a *de facto* moratorium on the technology that is currently supported by 193 countries.[71]

Lack of Biotech Literacy. Compounding these issues is the lack of biotechnology literacy in the general public, which is leading it to make decisions about the potential health and environmental impact of GM foods and other biotechnologies in response to emotional arguments, rather than a common understanding of the science. The International Technology Education Association (ITEA) identified the need for increased science literacy to inform this debate in its project "Standards for Technology Literacy."[72] Our conversations with industry, government, and academia representatives echoed the ITEA's conclusion that:

> We are a nation increasingly dependent on technology. Yet, in spite of this dependence, U.S. society is largely ignorant of the history and fundamental nature of the technology that sustains it. The result is a public that is disengaged from the decisions that are helping shape its technological future. In a country founded on democratic principles, this is a dangerous situation.[73]

Regulatory Pathways. Finally, there are undefined regulatory pathways for some potential new biotech products. While biotech firms in the medical care segment applaud recent efforts to make existing pathways more efficient -- such as a new FDA initiative that promises firms that develop novel or neglected disease treatments expedited reviews of their next drug -- there is no defined way to seek approval for bio-similar drugs (follow-on versions of biologic medicines developed by firms after patents expire) in the United States.[74] Also, FDA medical device regulators recently ordered direct-to-consumer, personal genomic-testing providers to cease operations, raising charges that the FDA is hampering the development of personalized medicine.[75] In addition, the Environmental Protection Agency (EPA) has yet to approve genetically-engineered microbes for use in bio-remediation.[76] The lack of harmonization in the way genetically-modified products are regulated around the world, highlighted by the well-publicized differences between the United States and the European Union on GM food products, also threatens to decrease trade and increase food costs.[77]

Additional Assessment of the Agriculture Segment

As noted above, the economic mechanisms at work in each of the biotech industry's segments, particularly the mechanisms used to fund research and development activities, are different. This section analyzes the agricultural segment in more detail, utilizing the return on investment (ROI) metric as well as business management concepts of firm behavior and economic theories about the role networks play as a source of innovation. We also examine the significant distortions in this market and recent efforts to capture positive externalities such as GM crops' ability to slow climate change. We were particularly interested in producers' monopoly power and competitive behavior, as price is a factor in farmers' adoption of GM seed and other biotechnologies. Given the need to also keep pace with climate change, we were also concerned with this segment's capacity to continue to innovate, including the ability of the market to incentivize investment in research, and the ability of small firms, which are increasingly the source of innovation for this industry, to enter this market.

New Competition Strategies Are Making Products More Affordable. Currently, the agricultural segment consists of the "big six" firms of Monsanto, DuPont, Syngenta, Bayer, Dow, and BASF, which also have non-biotech products. In addition to the "big six," there are about 30-40 small- and medium-sized firms dedicated to producing agricultural biotechnologies globally, many of which are focused on basic research.[78] These firms generate most of their profit through the sale of seeds, fertilizers and animal treatments such as hormones and antibiotics.[79] According to FAO, the markets for these products have been less price volatile than in recent years, enabling firms to generate sustained profits and returns on investment that exceed the weighted average cost of capital.[80] The industry average ROI for the past five years was 15.8.[81] A ratio greater than 10 indicates investors are achieving positive returns on their investments. Looking at this comparatively high ROI, one would expect the industry to attract more entrants and investment.

Despite these incentives, industry reports and anecdotes provided by industry members, suggests that the numbers of new entrants have not increased. Applying the "Five Forces" model that Michael Porter developed to study the competitive behavior of firms may offer one explanation. Patents have helped large firms to differentiate their products and increase barriers to entry. The largest industry players have also captured more of the "value chain" by horizontally integrating suppliers, including purchasing mines to produce the raw materials they need to produce fertilizer, herbicides, and insecticides.[82] The "big six" firm are also capable of limiting substitute products. For example, concern over GMOs is creating a growing market for "organic" substitutes, including non-GM products improved through cross-breeding or through "tilling" techniques, which use gene detection techniques to identify the best seed created through conventional seed breeding.[83] The "big six" firms are now considering adding tilling products to their line to maintain market-share. Although some analysts have concluded that the major six firms' share of market is not overly concentrated using the Herfindahl-Hirschman Index and the CR4 ratio of market concentration, their calculations rely on more readily available data for the larger global seed market, which includes both GM and non-GM products.[84] If you look at the market for GM seeds, which is the agricultural biotechnology (AgBio) segment's largest source of revenue, the industry looks oligopolistic. This would normally raise concerns about collusion. However, this does not appear to be the case.

A key mitigating factor appears to be that GM products in this segment, including Monsanto's Roundup herbicide, are coming off patent in the next ten years, allowing for potential generic manufacturers to enter the market. It still remains to be seen how the market will react but there are early indications that the "big six" are responding by competing on price. For example, DuPont is currently attempting to compete with Monsanto by offering a lower price for its GM seed. Large firms like Monsanto are focused instead on developing competitive strategies that could change the market in ways that would enable them to recapture more value from the buyers.[85] For example, they hope to develop personalized services for farms, such as detailed information about their fields to vary the type of seeds used. In addition to these competitive forces, the U.S. government has been closely watching the monopoly power of the largest firms, which also curbs collusive behavior.[86] The emerging price competition promises to lower the price of GM seed. This should assist in accelerating its adoption in developing countries.

But High ROI Is Not Attracting New Entrants. In a knowledge-based industry like biotech, another key metric is the ability of firms to fund basic research. Despite high levels of ROI, this segment is not attracting venture capital for firms that specialize in early-stage research. This discrepancy can be accounted for if one distinguishes between ROI earned by firms that specialize in basic research and the ROI for those that translate that research into products. While ROI is high for product development, the experimental nature of early stage research makes ROI for basic research comparatively low. While such disaggregated ROI data is not available, industry associations report that venture capital investors have moved out of early stage research to "more profitable" upstream product development.[87]

Moreover, the big six firms are also reducing their in-house research shops, which have had comparatively poor records of producing new innovations, and are relying instead on acquiring firms with promising new technologies. This raises concerns about the future innovative capacity of the industry. Industry associations and members that we interviewed pointed out that an overwhelming number of small AgBio firms that enter this segment operate with a business strategy aimed at being acquired by the "big six" firms and only have the funds to develop a single product.[88] Thus, their research is less experimental than it is directed by the need to investigate potentially profitable products that attract the major players. Industry member also said that the high cost of the regulatory process also forces some smaller innovative firms to merge with the big six firms.[89] The small number of new firms entering this segment is also a worrying trend if one looks at the industry through the "triple helix" theory of innovation, which suggests that the source of high-tech industries' innovative capacity has been a function of firms' ability to network and share information.[90] The absence of clusters of firms that specialize in agricultural biology suggests this segment's future innovative capacity is lower than the medical segment, which is highly geographically concentrated in Boston and San Diego.[91]

That said, growing public support in developing countries may create new entrants. Although neglected by the private sector, agricultural R&D in low-income countries continues to be one of the most productive investments, with ROIs between 30 and 75 percent.[92] The public sector, however, is stepping in, driven by social as well as developmental goals. For example, more than 27 percent of Korea's biotech industry is focused on agriculture and food production despite the fact that Korea has extremely limited amounts of arable land.[93] This makes sense when one considers that Korea imports 70 percent of its food requirements, resulting in a $13.2B annual food trade deficit, and has a policy to increase food security.[94]

New efforts to capture the externalities associated with AgBio products could also alter the future potential of this segment. For example, fear over the potential negative health and environmental impacts of GM seed has led to new labeling requirements and trade restrictions aimed at reducing current levels of consumption of GM products. Conversely, the United Nations has sought to incentivize the adoption of some GM crops because of their potential to slow the pace of climate change. For example, it is offering carbon credits to countries that promote the adoption of GM seeds that require less fertilizer, which reduces carbon emissions.[95] According to some expert projections, adopting nitrogen-use efficient technologies in the world's largest seven crops would be the equivalent of taking all the cars off the road in the U.S., UK and France combined.[96]

***Significant Market Distortions*.** Complicating these market and economic-based trends are the government regulations, subsidies and trade protections that influence this segment. In 2005, the U.S. government increased demand for agricultural products, particularly GM corn, by establishing the Renewable Fuel Standard (RFS), which mandates the use of biofuel.[97] The Farm Bill also funds nutrition assistance programs that have raised the number of consumers for GM food. On the supply side, the Farm Bill provides farmers subsidized services, including insurance, research, protections for some crops, and protections from price fluctuations for commodity growers (the vast majority of which use GM seed).[98] Other countries, especially the EU member states, have similar programs.[99] In sum, government intervention increases demand and reduces the cost of production, thus contributing to the positive ROI rates achieved by a few GM seed producers. But the desire of countries to protect their domestic agriculture markets has also resulted in significant trade barriers for GM products.[100] These trade barriers reduce the potential export market for GM products, which in turn, creates disincentives for AgBio firms to invest in researching new GM products.

BIOTECHNOLOGY SOLUTIONS FOR FOOD SECURITY

In this section, we provide an overview of the biotechnologies that are being developed across the entire industry that could help to address the growing food security-conflict challenge outlined above, and then assess how their adoption is likely to meet our future food requirements.

Technologies that Increase Food Quantity and Quality

The biotechnology industry has developed three major agriculture and aquaculture techniques that speed up living organisms' natural ability to evolve and adapt to their environment in ways that increase the quantity of food an organism produces, the nutritional quality of that food, and its ability to withstand transportation and distribution.

Genome Mapping for Breeding. As noted above, the biotechnology industry is using a breakthrough technology -- the ability to map the genes in an organism and "read" the genetic instructions that give it specific traits -- to identify advantageous genes that can be used to breed plants and animals with desirable qualities.[101] This technique, called molecular marker-assisted breeding, builds upon centuries of conventional breeding to bring about beneficial adaptations. For example, in plant crops, specific genes or "genetic controls" can be turned off, such as the gene that produces the enzyme that causes apples to brown when exposed to air.[102] However, the benefits of this approach are limited because undesirable genes can be transferred along with desirable genes and other desirable traits can be lost.[103]

Genetically Modified Organisms. To limit this uncertainty, the industry has developed genetic engineering techniques that involve transferring genes between organisms to introduce a new trait that is not present in the organism or when breeding methods are very difficult or time consuming.[104] Scientists take DNA molecules from different sources and combine them into a single molecule through a technique called recombinant DNA technology.[105] This allows them to create new crop strains that can resist pests and herbicides, survive harsh climatic conditions such as drought, and increase nutritional value and harvest yield. In 2013, 90 percent of the corn and cotton crops and 93 percent of the soybean crop produced within the United States came from GM seed.[106] Twenty-nine countries now plant GM seed although the majority of GM corn and soybeans was used as feed for livestock.[107] Second-generation GM seed now in development aims to "stack" a range of desirable traits in one seed so that crops can have many valuable adaptations, such as salt tolerance, nitrogen efficiency, and water efficiency.[108]

Precision Farming. Precision Farming is an emerging technique that combines land and climate information using Global Positioning and Geographical Information Systems with the biotechnologies outlined above to improve crop production. Traditionally, farmers plant a crop in a field as one uniform unit, using the same amount of seed and fertilizer, regardless of variations in soil type, moisture, or climate. By analyzing the geology, hydrology, and climate trends with remote sensing data, farmers can now adjust the type of seed and fertilizer for specific sections of their field based on its distinctive characteristics. In addition, after the crop is planted, the farmer can monitor the health of his crop using remote sensing equipment. If a section is stressed, the farmer can identify and treat the cause by applying a specific remedy to that exact spot. With this comprehensive information, farming is less resource-intensive and therefore less expensive and less harmful to the environment. Precision Farming is also projected to increase crop yield; the industry believes that it can double yields by 2030 to 300 bushels an acre from the current national average of 150-160.[109]

Technologies that Increase Resources Needed for Food Production

Today, seventy percent of global freshwater is used for farming.[110] With current water management practices, the global agricultural sector would need to double the amount of water available to feed the world by 2050.[111] Land availability is also a significant issue.[112] Future food production necessitates some expansion of arable land but the existing amount of arable land is expected to decrease significantly by 2050 due to climate change and urbanization.[113] The biotechnologies listed below offer some solutions to maximize our limited resources:

Aquaculture Filtration. The worldwide expansion of aquaculture, also known as fish or shellfish farming, currently threatens farmland and nearby surface waters because it releases harmful discharge in surface waters and lands located near fish farms.[114] Aquaculture filtration is a biotechnology that employs bio-filters to internally treat polluted waters with dissolved organics and ammonia.[115] A 500-ton annual production facility can require as much as 2.5 billion gallons of fresh water per year but with a zero-discharge system, this figure drops to half a million gallons of water with zero pollution. This is a 5000-time reduction in water usage.[116]

Salt Tolerant Plants. Given limited freshwater sources, researchers are developing canola, rice, cotton, and tomato crops that are salt resistant in order to utilize brackish–water and land for farming.[117] Seventy-seven million hectares of agricultural land (which exceeds the amount used globally to produce the $28B soybean crop) is not being used, or is producing suboptimal yields, due to salinity.[118] Salt tolerant plants can use salty water and rehabilitate salinized land.[119]

Water Efficient and Drought Tolerant Plants. By identifying the genes in sunflowers that make them water efficient and drought tolerant, scientists have engineered other crops to express these same traits.[120] In the case of cotton, crop yields using water efficient GM plants on dry lands are nearly the same as non-GM irrigated crop yields.[121] Currently, 40 percent of world food production occurs on irrigated land, which is less than 17 percent of the farmland now in use.[122]

Nitrogen Efficient Plants. Modern agricultural is heavily reliant on fertilizers that provide plants with macronutrients, especially nitrogen, phosphorous, and potassium. For example, the production of one bushel of corn requires 16 pounds of nitrogen, 12 pounds of phosphorous and four pounds of potassium.[123] Globally, farmers spend $60 billion annually on nitrogen. Unfortunately, half of that investment is lost due to runoff. Furthermore, the use of nitrogen fertilizer is the second largest source of greenhouse gas emissions.[124] Arcadia Biosciences, a California-based firm, has developed commercially-available nitrogen-efficient rice, wheat, barley, maize, canola, and sorghum crops that produce comparable yields but use 50 percent less nitrogen fertilizer.[125] They are currently developing seven other nitrogen-efficient crops, including potatoes and fruit trees.

Bioremediation. U.S. factories release over 3 million tons of toxic chemicals into the land, air, and water annually. This results in the loss of 15 million acres of arable land every year.[126] Bioremediation technologies that use microorganisms that speed up the natural rate of biodegradation could help reclaim this land.[127] Unlike conventional remediation, which relies on soil removal and disposal in a toxic landfill, bioremediation eliminates the toxic chemicals on site by converting it to carbon dioxide and water.[128] When completed, the microbes used in the remediation process naturally die and are replaced by microbes native to the area.[129] While this technology has been used to clean up the 1989 Exxon Valdez oil spill in Alaska, two factors are still limiting its wider commercial application. First, the speed by which microbes operate on a particular site varies based on the climate and soil conditions at that site and this variability has deterred demand. More critically, the EPA has not approved the use of genetically-engineered microorganisms due to their potential impact on the biodiversity of neighboring sites.[130]

Bio-Mimicry. Bio-mimicry is a nascent technique that attempts to imitate biological processes to develop new production and transportation processes, and new materials that could also be applied to increase arable land.[131] Some pilot projects are looking at ways to promote agriculture in urban areas and expand perennial grain cropping, or permaculture, which is a form of agriculture developed to mimic natural systems.[132]

Can the Biotech Industry Address the Food Insecurity Challenge?

The increase in available biotechnologies that can boost the raw productivity of agriculture raises a key question: will we be able to increase food production by 70 percent over the next 30-40 years by adopting existing technologies or do we also need to continue to foster the invention of additional disruptive innovations? Recent FAO reports suggest that adoption strategies are critical but may not be sufficient.

The FAO believes that 90 percent of future growth in global crop production will need to come from continued adoption of crop intensification technologies that produce higher yields on existing lands, in the developing countries in Africa, Asia, and Latin America.[133] Recent statistics compiled by the International Service for the Acquisition of Agri-Biotech Applications are a positive indication that the adoption of GM seed is increasing significantly in those regions, in spite of its higher cost. In 2011, the use of biotech crops in the developing world outpaced the developed world for the first time.[134] Globally, 18 million farmers planted 160 million hectares of biotech crops in 2011 in 29 countries.[135] Nineteen of those countries were developing, accounting for 94.1 million hectares.[136] According to industry analysts, if these GM crops had not been used in 2011, farmers would have required nine percent more agricultural land in the U.S., 25 percent more land in Brazil, and 28 percent more land in the EU to reach the same production levels.[137]

These analysts attribute the rapid adoption of GM seed to public support from countries like Brazil and China, which are developing and marketing it. Another reason for the rapid uptake of crops with genetic modifications in developing countries is that governments, international organizations, non-profit groups like the International Service for the Acquisition of Agri-Biotech Applications, and private companies have been willing to support technology donation and tech transfer programs aimed at increasing small-scale farmers' access to GM technologies at affordable prices.[138] For example, the partnership that the U.S. Agency for International Development (USAID) helped broker between Monsanto and the Kenyan Agricultural Research Institute (KARI), in which Monsanto provided patented technology free of charge to Kenya and other African countries to develop disease-resistant sweet potatoes, was designed to increase access to biotech applications in "orphan" crops of importance to small-scale farmers and poor consumers.[139]

Some industry members believe that the adoption of nitrogen use-efficient (NUE) crops is a second potential "game changer" that could continue to raise crop yields. According to Arcadia Biosciences, the traditional fertilizer industry is promoting the adoption of NUE crops because it reduces the amount of nitrogen farmers need to buy, making it more affordable.[140] This is opening up potential markets in Africa and other developing regions where farmers did not previously use fertilizer, which promises to make agriculture in those regions more productive. Arcadia Biosciences also gifted NUE rice to the African Industrial Technology Consortium to increase its affordability. Despite these gains, industry members view anti-GM activism as a potential threat to the future adoption of biotech crops. Furthermore, the industry members we interviewed believe that climate change will continue to demand the development of new types of GM crops, particularly those with stacked traits like heat and salt resistance. They believe that climate change is a major threat to food security because the agricultural industry is following a "just in time" production model. This threat, they add, is compounded by the impact of environmental pollution from industry and aquaculture.

Leading U.S. academic institutes researching global food security such as the U.C. Davis World Food Center, the Stanford University Center on Food Security, the Aspen Institute and the Norman Borlaug Institute for Global Food Security at Texas A&M also identify a need for continued biotech innovation.[141] For example, at the 9th Annual Ag-Issues Forum in February of 2014, Julie Borlaug of the Texas A&M Agri-Life Research and Extension Center urged attendees to educate the public about the need for continued biotechnical advances in agriculture to feed a growing world population.[142] In economic terms, climate change and environmental degradation are shifting the entire supply curve for food products to the left due to the elimination of key factors of production. Ideally, the development of new biotechnologies would counter that effect and help move the supply curve further to the right to meet additional demographic growth.

While increasing raw food production is necessary to keep pace with climate change, improving the food supply chain is equally critical.[143] "In some countries, food wasted in post-harvest losses can reach levels as high as 40 percent because of gaps in the food chain infrastructure, including lack of proper storage facilities to protect against the external environment and pests."[144] Engineering foods that maintain a longer shelf life and have increased transport resiliency would also help to remedy this logistical challenge.

CONCLUSIONS AND RECOMMENDATIONS

In conclusion, meeting our future food security needs will not only require us to continue to employ existing biotechnologies but to develop new, innovative products. To achieve these two goals, we have identified eight recommendations. Three are designed to ensure the adoption of existing agriculture biotechnologies does not slow down, four are designed to help ensure the industry is able to attract new entrants that can develop innovative products and one is aimed at reclaiming agricultural land.

Recommendations to Maintain Demand for Existing Agricultural Biotech Products

As noted above, government and NGO tech transfer and education programs have been effective in accelerating the adoption of GM crops over the last decade by increasing farmers' awareness of "second-generation" traits such as greater yield and drought resistance which are more cost effective than earlier GM products as well as non-GM crops. We also believe that price competition in the industry will also help to retain these gains. However, anti-GMO campaigns are starting to influence consumers to the point that they now threaten to slow or even reverse recent increases in adoption of GM products.[145] To address this issue, the national industry association has launched a new Website to answer consumers' questions.[146] We believe the following steps should also be taken:

Recommendation 1: Launch a Biotech Literacy Campaign. To date, biotechnology education programs have tended to concentrate on producers. We recommend that the U.S. government launch a new public education program that explains complicated biotech or scientific terms so that consumers can make educated, science-based judgments about the safety of biotech products. This campaign should also elevate awareness of the growing threat of food insecurity by highlighting all of the positive externalities or benefits that AgBio products provide to address this threat, including higher nutritional content, shelf stability, and the ability to use less hormones and antibiotics in agriculture. A parallel international campaign should also be launched in regions where foreign governments or NGOs are conducting information operations designed to dissuade consumers from using biotech products through emotional appeals or unsubstantiated claims about their safety.

Recommendation 2: Put a Public Face on the Government's Efforts to Support AgBio R&D. Appointing a high-profile member of the private sector, or high-level government official, to serve as a "Biotech Czar" would be a cost-effective way to raise the impact of an AgBio awareness campaign. Additionally, it would have the added value of focusing and coordinating the work of the 20 plus U.S. science and technology agencies that support agricultural biotech research or product development. This appointee could also support the Office of Science and Technology Policy's efforts to raise public awareness of the importance of developing the U.S. bioeconomy by attracting members of the media, foundations, and businesses that might be willing to support literacy campaigns or sponsor special events such as the Smithsonian Institute's recent "Birth of Biotech" exhibit at the American History Museum.[147]

Recommendation 3: Create Voluntary GM Labeling Guidelines. Currently 64 countries, to include all 28 members of the European Union, require labeling of foods that contain GM products.[148] The United States does not, but that is changing. Vermont recently passed legislation that would start requiring GM labeling in July 2016. Connecticut and Maine also have labeling laws that will trigger if neighboring states put similar regulations in place and 23 other states are currently considering similar labeling bills.[149] The Grocery Manufacturers Association, "is lobbying for a law that would oblige the FDA to test all new GM traits before they reach the shelves and to finalize guidelines for a voluntary labeling regime that would preclude state laws that mandate labeling".[150] Since consumer product labeling can serve as an important means of educating consumers, we recommend that the administration create voluntary labeling guidelines to avoid a patchwork of labeling laws that would force food firms to separate GM from non-GM ingredients, which could disrupt the supply chain, increase food prices, and amplify anti-GMO rhetoric that questions the safety of biotech products.

Recommendations to Promote Innovation

Given that experts in food security believe that agriculture will need to become even more adaptive to keep pace with climate change, we believe that several new initiatives are warranted to promote the future innovative capacity of the industry.[151]

Recommendation 4: Support Basic Research. Academic research that is not constrained by profit considerations is a critical investment in future, disruptive technologies. We believe that the U.S. Government must not abdicate its historical role as the largest global provider of biotech research funding given that it is the lifeblood of knowledge-based industries. In the current political environment, we believe two cost-neutral steps could be taken to increase the productivity of early-stage biotech research and incentivize the private sector to invest in it. As noted above, much early-stage biotech research is duplicative. The biomedical segment of the industry is starting to work together to reduce these inefficiencies by embracing precompetitive alliances where firms work with their competitors to investigate new platform technologies and then make that information available to the entire industry. The U.S. Government could encourage the AgBio segment to adopt similar practices. For example, it could partner with foundations to sponsor a web portal to share proprietary clinical and field trial data and provide incentives to encourage participation, such as fast-track regulatory approval. Such initiatives could also promote some very promising potential biotechnologies found in areas that converge with other disciplines. In the case of AgBio, leveraging big land and climate data could double crop yields and reduce environmental damage.[152] Instead of individual companies competing for this information, U.S. national labs could provide consolidated data to the entire industry while ensuring the privacy of farmers' data.

Such measures promise to increase ROI for venture capital and angel investors who are currently reluctant to risk investing in basic research in an industry where the average cost and time to bring a new AgBio product is $136 million and 10-15 years.[153] In the meantime, we support calls to reduce this risk by making the Research and Experimentation Credit ("R&D credit") that expired in December permanent.[154] However, we also support the administration's position that the cost of these tax credits should be offset by closing tax loopholes.[155]

Recommendation 5: Establish Biotech Agricultural Incubators. With startups unable to find funding, there is an increasing tendency of small firms to resort to "exit" business strategies that depend on mergers with the "big six" AgBio firms. In doing so, they limit their research to areas of interest to the "big six." To encourage new entrants, we recommend that states that host research universities with AgBio programs (e.g., California, Texas, North Carolina) create or extend their existing biotech incubators to focus on fostering the creation of new AgBio firms. Small, poorly resourced in the AgBio segment would benefit if such incubators hired lawyers with agriculture-related regulatory expertise, as well as experts in business development, marketing, and advertising. To support field-testing, we also recommend that public entities grant these incubators long-term land leases that are free or at substantially reduced prices, or perhaps even permanent land grants.

These incubators would also increase networking opportunities, a phenomenon that has been a source of strength for other high-tech industries. Given the potential for collaborations between AgBio and other disciplines to create more novel and disruptive technologies, we believe these incubators should also help AgBio firms forge networks with a wider range of start-ups firms. One proven mechanism to do this is to secure public or private sector support to purchase cutting edge research equipment that other firms can afford. University-based incubators that have big data capacity could, for example, be attractive to IT firms.

Recommendation 6: License Biotech-Agriculture Resources for Sale on a Secondary Market. As a further incentive for biotech companies to enter the market and innovate, we recommend that the U.S. Government extend a recent FDA initiative directed at biomedical firms that has helped to incentivize the research and development of novel products to USDA and EPA. Under this new initiative, firms that develop a novel product or a vaccine for a neglected disease receive "fast track" regulatory approval for their next product. Moreover, these firms can sell these valuable fast track authorities to their rivals to raise capital.[156]

Recommendation 7: Phase Out Subsidies and Trade Barriers that Have Unintended Impacts. While it would be challenging to re-legislate the Farm Bill in the current political environment, eliminating agricultural subsidies would make the agricultural industry more price sensitive. This would encourage farmers to adopt more efficient technologies like GM crops that require fewer inputs like pesticide and fertilizer, and have higher yields. If Congress were to eliminate these subsidies (and award the administration fast track negotiation authority for the TPP and the possible U.S.-EU trade agreement), it would also put U.S. trade negotiators in a stronger position to secure agreements from foreign governments to lower their barriers on GM products. If these barriers to trade were removed, the potential size of the market for AgBio products would increase, providing more incentives for firms to innovate. Eliminating the subsidies on corn would also have the secondary effect of reducing its use in biofuel production. This would create incentives to shift to non-food, cellulosic crops and help the current competition that exists between the biofuel industry and agriculture for land and water.

Additional Recommendation to Increase Food Security

Recommendation 8: Use Bioremediation Technologies to Increase Arable Land. Finally, we could increase the availability of arable land in the United States if we were to enable remediation firms to utilize emerging bioremediation technologies. As noted above, the EPA has not yet licensed genetically-modified organisms (GMOs) due to concerns over their potential impact on the environment. While terminator technologies that make food crops sterile are controversial given that they help firms extract value from farmers by requiring them to buy seed on an annual basis, the U.S. should explore their viability in bioremediation as a means to limit the potential unintended impact on environments adjacent to toxic sites.

Taken together, these eight recommendations would establish the incentives and investments necessary to ensure the AgBio segment continues to grow and has the potential to develop innovative responses to our increasingly pressing food security challenges. The majority of our recommendations leverage market forces and private sector support. While it is challenging to implement new federal programs in this fiscally austere environment, we believe that they are relatively modest investments when compared to the emerging threats to our security.

[1] A biomolecule or biogenic substance is any molecule that is produced by a living organism, including large macromolecules such as proteins, polysaccharides, lipids, and nucleic acids.

The above definition is based on information gathered through the course of the current Industry Study and the National Bioeconomy Blueprint.

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