## Biodefense Net Assessment

## Causes and Consequences of Bioeconomic Proliferation: Implications for U.S. Physical and Economic Security

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Prepared for
Department of Homeland Security
Science and Technology Directorate

#### HOMELAND SECURITY STUDIES AND ANALYSIS INSTITUTE

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#### Task 09-45, Biodefense Net Assessment

The purpose of the task is to provide fresh perspectives of biodefense to senior decision makers.

The results presented in this report do not necessarily reflect official DHS opinion or policy.

This analysis was conducted as part of the 2012 policy net assessment required under Homeland Security Presidential Directive 10 (HSPD-10), *Biodefense for the 21<sup>st</sup> Century*. These assessments are meant to provide senior level decision makers with fresh, nonconsensus, perspectives on key issues underlying the Nation's biodefense. As such the assessments reflect the perspectives of the authors and not necessarily those of their host institutions, nor the Department of Homeland Security, nor any other Federal, state or local agency. It is our sincerest desire that the content of this report will enhance the dialogue and debate about U.S. biological defense strategies and capabilities.

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#### **PUBLISHER'S NOTE**

When the White House articulated the nation's first comprehensive biodefense policy in HSPD-10 (Biodefense for the 21st Century), it realized that biological threats and the policies and strategies to defend against them would evolve in time. Recognizing the need to periodically review and update the nation's biodefense policy and strategy, HSPD-10 calls for "a periodic senior-level policy net assessment that evaluates progress in implementing this policy, identifies continuing gaps or vulnerabilities in our biodefense posture, and makes recommendations for re-balancing and refining investments among the pillars of our overall biodefense policy."

These Biodefense Net Assessments (BNAs), as they have come to be known, are sponsored by the Department of Homeland Security and managed by the Homeland Security Studies and Analysis Institute. Their goal is to provide independent, fresh perspectives on longer-term strategic issues that can fundamentally change the nation's understanding and response to the threat posed by bio-terrorism. To accomplish this, the BNA uses a three step process: (1) identify unresolved strategic questions with the largest impact; (2) identify and engage principal investigators (PIs) who are knowledgeable in the area but can still bring a fresh, independent perspective to the issue; and (3) provide an extended process of discussions and reviews with the PIs as they accomplish their work to ensure quality, but being careful not to 'steer' the analysis. A key element of the BNA process is the Executive Review Panel (ERP), which is composed of respected members of the biodefense and related communities in government, academia, and the private sector. ERP members and their affiliations are listed below.i The PIs interacted with the ERP as a whole and also had extensive interactions with their assigned mentors.

To date, one cycle of BNAs (2004-2008) is complete and the second cycle (2009-2012) is underway. This current study is part of that second cycle and focuses on the critical question of how to detect bio-attacks involving not only the most likely agents but also "unexpected or novel" agents. Since the goal of the ERP is to provide decision makers with fresh, non-consensus perspectives, the report reflects the author's viewpoints and may or may not reflect the individual or collective views of the ERP.

Specifically, the "charge" as given to the principal investigator was:

Examine the strategic implications of international bioeconomic proliferation on the security and strategy of the United States.

#### **Background**

Biotechnology is becoming increasingly de-skilled and less expensive, leading to a proliferation of localized innovation around the world. In addition to major investments by growing economic powerhouses India and China, other developing countries such as Indonesia, Pakistan, and Brazil are equally intent on developing domestic biotech research and development capabilities. All of these countries are interested initially in producing drugs for diseases that predominantly affect their citizens, a project that requires a particular infrastructure and set of skills. Yet those same skills can be used to develop other applications, from fuels and materials to weapons, all of which can serve as a lever to increase power and presence on the world stage, thereby enabling developing countries to become rivals to the US both regionally and globally.

Economic demand will serve as a driver for ever greater proliferation of biotechnology. Today, in the US, revenues from genetically modified systems contribute the equivalent of almost 2% of GDP, and are

growing in the range of 15-20% per year. China, among other countries, is not far behind and is following explicit government policy to substantially increase its independent, domestic development of new biological technologies to address such diverse concerns as healthcare, biomass production, and biomanufacturing. As is already the case in many other industries, trade between developing nations in biotech may soon exceed trade with the US. Therefore, among the challenges the US is likely to face in this environment is that the flow of technology, ideas, and skills may bypass US soil. Moreover, because skills and instrumentation are widely available, biotechnological development is possible in unconventional settings outside of universities and corporate laboratories. The resulting profusion of localized and distributed innovation is likely to provide a wide variety of challenges to US security, from economic competition, to intelligence gathering, to the production of new bio-threats

#### Scope of this study

In examining these strategic implications of unconventional Biotechnology, the Principal Investigator should:

- Evaluate the drivers for engaging in Unconventional Biotechnology activity globally.
- Develop an assessment of economic development as a driver of proliferation, in particular the dependence on, and investment in, biotechnology in potential rival countries such as China, India, Indonesia, Pakistan, and Brazil.
- Based on an understanding of these drivers, develop an assessment of what skills and technologies are likely to be available in rival countries and consider what effects US regulation might have on the transfer of skills and activity offshore.
- Address how steps taken by would-be rival countries can be used inform the US about increasing
  its own physical and economic security. In other words, what are potential rivals doing that
  should be included in US strategy?

Certain countries explicitly investing in biological technologies for domestic economic development have geographical or ideological overlap with non-state groups that aim to cause both physical and economic disruption in the US. In addition, surplus labor in a number of developing countries can lead to the development of "hacking cultures" in which technically minded and educated individuals are employed in gray or explicitly illegal enterprises as the only way to earn a living. Some of those individuals might be expected to learn or apply biotech skills. We suggest that the PI should consider:

- How realistic is the potential for transfer of skills or technology from general economic development to organizations seeking to threaten the US?
- In the context of the accelerating proliferation of biological skills and technology, how should the US improve its intelligence gathering capabilities?

Accelerating proliferation will lead to greater uncertainty in assessing emerging threats. The PI should also address:

- Where are the surprises going to come from?
- With the increase in demand for biotechnological skills and products, how can the US learn to adapt to technological transformation that might emerge from all corners of the globe?
- Can the US use relationships between third parties to map out concentrations of skills and technologies that may serve as incubators for surprise?

<sup>i</sup>The members of the Executive Review Panel are:

- Segaran Pillai, Ph.D., Biological and Chemical Countermeasures Program, Science and Technology Directorate of the Department of Homeland Security
- Michael Callahan, M.D., DTM&H, Defense Advanced Research Projects Agency/Defense Sciences
   Office
- Seth Carus, Ph.D., Deputy Director, Center for the Study of Weapons of Mass Destruction, National Defense University
- Richard Danzig, J.D., Ph.D., Sam Nunn Prize Fellow, Center for Strategic and International Studies
- David Franz, D.V.M., Ph.D., Vice President & Chief Biological Scientist of Midwest Research Institute
- Wendy Hall, Ph.D., Director of Bioterrorism Policy in the Policy Directorate of the Department of Homeland Security
- Robert Hooks, Deputy Assistant Secretary and Director, Health Threats Resilience Division, Office of Health Affairs, Department of Homeland Security
- Thomas Inglesby, M.D., Chief Operating Officer and Deputy Director, Center for Biosecurity of University of Pittsburgh Medical Center
- Norm Kahn, Ph.D., Program Manager, Counter-biological, Office of the Chief Scientist, CIA
- Carol Linden, Ph.D., Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- Ben Petro, Ph.D., Director for Biodefense, White House Homeland Security Council
- John Vitko, Ph.D., former Director of the Department of Homeland Security Chemical and Biological Division, now retired
- Margaret (Jo) Velardo, Ph.D., Director of Research, Homeland Security Studies and Analysis Institute

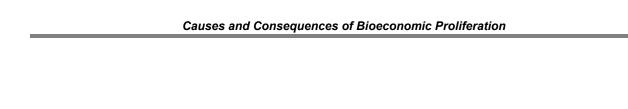


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Dr. Carlson is fundamentally interested in the role of biology as a human technology. He has worked to develop new biological technologies in both academic and commercial environments, focusing on molecular measurement and microfluidic systems. Carlson is the author of the book "Biology is Technology: The Promise, Peril, and New Business of Engineering Life", published in 2010 by Harvard University Press. Dr. Carlson earned a doctorate in Physics from Princeton University in 1997.



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Robert Carson, PhD

# CAUSES AND CONSEQUENCES OF BIOECONOMIC PROLIFERATION: IMPLICATIONS FOR U.S. PHYSICAL AND ECONOMIC SECURITY

**December 31, 2011** 

Prepared for
Department of Homeland Security
Science and Technology Directorate

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**HSI Publication Number: RP09-45-05** 

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#### **EXECUTIVE SUMMARY**

Biotechnology is becoming increasingly de-skilled and less expensive, leading to a proliferation of localized innovation around the world. Governments see biotechnology as an opportunity for economic development and a route to increased influence. In addition to major investments by growing economic powerhouses India and China, countries such as Indonesia, Pakistan, and Brazil are intent on developing domestic biotech research and development capabilities. States can use this new knowledge to increase their power and presence on the world stage, thereby becoming rivals to the United States regionally or globally. Smaller groups and individuals will use biology for their own ends, and those ends will be very diverse. To the extent that a biotechnological threat landscape can be identified in the coming decades, it consists of both physical and economic threats.

A broad proliferation of biotechnology into the global economy is well underway. The flow of technology, ideas, and skills will increasingly bypass U.S. soil, making monitoring difficult. Moreover, because skills and instrumentation are increasingly widely available, biotechnological development will proceed in unconventional settings outside of universities and corporate laboratories.

Both technological change and market demand are driving proliferation. The technologies used to read and write DNA are doubling in productivity every 18 months, while the cost of those same technologies is falling even faster. Overall, productivity in a wide variety of fundamental laboratory operations has been doubling roughly every 18 months for two decades. Biotech employment has been growing rapidly for the last decade, an indicator of a large widespread demand. This new skilled labor pool facilitates the commercial outsourcing of many tasks—often across international borders—that once required one or more PhD-level researchers when done in house. The number of biotech firms in developing countries engaged in collaborations and contractual arrangements with partners in other developing countries is now expanding rapidly.

The U.S. bioeconomy is the global leader with revenues of \$250 billion annually, or just under 2% of Gross Domestic Product (GDP). While the United States derives the largest absolute revenues, the fractional share of GDP derived from biotechnology, and thus importance to the state, is higher in both China and Malaysia (2.5% of GDP). Absolute revenues in both countries are also growing at more than 20% annually. India is a relative latecomer to biotech, and earns only 0.2% of GDP from biotech, but the country is investing heavily and more than 60% of its biotech revenues already come from exports. Pakistan receives about 1.6% of its GDP from genetically modified cotton.

All countries examined in this study, with the exception of Pakistan, are educating large numbers of students to satisfy rapidly increasing labor demand. At some point in the future, regardless of the country examined, the demand for biotech labor will saturate as a natural consequence of economic development. The resulting surplus skilled labor may find employment in activities deemed less desirable by governments. This has happened in many fields over the years, including software development and chemistry, and results in parallel technology development programs supplying everything from illicit drugs, to submarines, to computer viruses.

In none of the countries directly examined in this survey are there national mechanisms to track the number of biotech firms or labor (surplus or otherwise). When combined with the torrid pace of economically-driven proliferation, this lack of information and awareness will eventually lead to surprises. In the context of this report "surprise" means an innovation by a particular actor that could not be easily foreseen by tracking the prior development of that actor and that may pose a risk to U.S.

interests; i.e., a threat. Biotechnological innovations might be produced by a state, small group, or even an individual. Producing such innovation will require skills, information, and a sufficient infrastructure. Thus, the potential for surprise can be gauged by measuring progress in those variables within countries of interest. This report presents initial efforts to develop metrics to assess such progress.

The overall conclusions of this report are that (1) the U.S. is likely to see biotech innovation coming from many diverse sources over the next decade (given the economically-driven global proliferation of biotechnology); that (2) some of those innovations are likely to constitute threats; and (3) there is too little effort presently directed at assessing information that would help determine the likelihood and nature of those innovations. Following the arguments developed in the main body of the text, this report makes the following recommendations:

- 1. The governments of the United States, Canada, and Mexico should consider gathering bioeconomic data about domestic labor, companies, and sectors via the North American Industry Classification System (NAICS). There is at present no NAICS code for biotechnology, thus limiting the accuracy of any U.S. government estimation of biotech economic activity even within U.S. borders.
- 2. The U.S. government should consider formally assessing customs tracking category data to understand better which chemicals and what equipment is going where.
- 3. The U.S. government should use the upcoming 2011 Review Conference for the Biological and Toxic Weapons Convention (BWC) as an opportunity to expand international discussion of the bioeconomy. Encouraging the reporting of state estimates of biotech economic activity would further one goal of the National Strategy for Countering Biological Threats, namely to revitalize the BWC by "promoting transparency about legitimate activities".
- 4. The U.S. government should vigorously encourage domestic firms to consider overseas sales. When overseas markets can be supplied by U.S. firms then (a) the domestic bioeconomy grows, (b) foreign development of competition and capability is forestalled, and (c) sales data provide a way of monitoring the focus and pace of research.
- 5. Conversely, the U.S. government should do as little as possible to discourage exports. Onerous export restrictions or excessive bureaucracy will increase economic displacement primarily in the form of trade that bypasses the United States—with a consequent decrease in transparency.
- 6. The U.S. government should seek to make or enforce level-playing field international trade agreements. An immediate item for consideration under the WTO treaty should be China's indigenous innovation requirement for government contracts.
- 7. The U.S. government should avoid regulatory actions that restrict domestic access to biological tools and technologies. Realizing long-term security benefits that derive from widespread domestic innovation in biological technologies requires that individuals and small organizations have continued access to biological technologies. Above all, the U.S. government should avoid actions that create perverse incentives for black markets.
- 8. The U.S. government should base biosecurity policy upon data. Because the international proliferation of biotech skills and materials is demonstrably driven by economics, the U.S. government should fund an ongoing assessment of the investment in, and the growth of, the international bioeconomy.

#### INTRODUCTION

Biotechnology is becoming increasingly de-skilled and less expensive, leading to a proliferation of localized innovation around the world. Governments see biotechnology as an opportunity for economic development and a route to increased influence. In addition to major investments by growing economic powerhouses India and China, countries such as Indonesia, Pakistan, and Brazil are intent on developing domestic biotech research and development capabilities. These states are interested in increasing crop yields or in producing drugs for diseases that predominantly affect their citizens, projects that requires a particular infrastructure and set of skills. Yet those same skills can be used to develop other applications, from fuels and materials to weapons. Governments can use this new knowledge to increase their power and presence on the world stage, thereby becoming rivals to the United States regionally or globally. Individuals and smaller groups will use biology for their own very diverse ends.

The diffusion and local development of biotech skills is being driven by economic demand. Today, U.S. revenues from genetically modified (GM) systems are the equivalent of 2% of Gross Domestic Product (GDP), and are growing at 15–20% per year. China, among other countries, is not far behind and is following explicit government policy to substantially increase its independent, domestic development of new biological technologies. China expects biotechnology to have impacts across society in areas such as health care, biomass production, and manufacturing. Similarly, India, Pakistan, and Malaysia all have government directed and funded biotechnology plans for education, research, and commercialization.

Biosecurity and biodefense are often viewed in the context of state-sponsored bioweapons development, bioterrorism, and securing laboratories and disease stocks. Quite apart from such programs, a broad proliferation of biotechnology into the global economy is already underway. First and foremost, biotechnology is seen by many governments as a means to bootstrap into a high-tech, exportdriven economy. As is already the case in many industries, trade between developing nations in biotechnology may soon exceed trade with the United States. In this environment the flow of technology, ideas, and skills bypasses U.S. soil making monitoring difficult. Moreover, because skills and instrumentation are increasingly widely available, biotechnological development will proceed in unconventional settings outside of universities and corporate laboratories. The National Strategy for Countering Biological Threats (National Strategy) explicitly acknowledges both this challenge and the consequent opportunity: "From cutting-edge academic institutes, to industrial research centers, to private laboratories in basements and garages, progress is increasingly driven by innovation and open access to the insights and materials needed to advance individual initiatives. We must support the ongoing revolution in the life sciences by seeking to ensure that resulting discoveries and their applications, used solely for peaceful and beneficial purposes, are globally available." The resulting profusion of localized and distributed innovation is likely to provide a wide variety of challenges to U.S. security: from economic competition, to intelligence gathering, to the possibility of new biothreats.

This paper explores the implications of international bioeconomic proliferation for U.S. physical and economic security. I begin with an evaluation of the technical and economic drivers behind biotechnology's proliferation. Based on open source information, I describe biotechnology proliferation in Pakistan, India, and China. Finally, I discuss several implications for the United States arising from bioeconomic proliferation and conclude with recommendations.

Organization: This paper is a data-driven analysis of trends in biotechnology and consequent implications for U.S. security. Where possible, I identify quantitative metrics that may serve as ongoing indicators of country-specific progress toward developing domestic biotechnological capabilities.

#### DRIVERS FOR PROLIFERATION

#### **Technical Drivers**

#### **Exponential Productivity Increases**

Nature improves organisms through trial and error (random mutations and shuffling of genetic instructions followed by a survival test). This design method generally produces change slowly. Since the discovery that DNA carries genetic instructions, and since learning how to manipulate genes in the laboratory, scientists have accelerated change by simply borrowing valuable traits from one organism for use in another. This is far speedier than evolution, but until recently has exhibited a timescale on the order of years for the various steps: locate an organism with the desired trait, pinpoint instructions for said trait within the genome, excise and transfer DNA to new organism successfully, grow and validate new organism. Today, many useful traits are completely understood to the level of individual genetic instructions. With this information, it is no longer necessary to physically bank genes in cold storage. Instead, instructions and programs can be stored as information alone and written only when desired. This methodology has reduced the timescale for creating new genetic programs to mere weeks.

The technologies for reading and writing DNA are quantitative metrics for the ability to create genetic programs. These technologies are becoming exponentially more capable and exponentially less expensive, leading to a broad proliferation of access around the world. The cost of synthetic genes (writing) is falling by half approximately every 18 months, while the cost of sequencing (reading) is halving every 12 months. These trends have existed for at least 20 years and there is no reason to expect any divergence in the next 5 years. (See Figure 1.)

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Carlson, Biology Is Technology.

#### Productivity in DNA Synthesis and Sequencing 1E+10 Synthesis Synthesis & Sequencing Productivity 1E+09 Productivity Integrated Circuit Productivity [# transistors / chip] Sequencing 1E+08 Productivity person / day] Integrated Circuit 1E+07 Productivity 1E+06 1E+05 bases / 1E+04 1E+03 1E+02 1E+01 1965 1970 1975 1980 1985 1990 1995 2000 2005 2010 2015 Year

#### Figure 1. Exponential Productivity Improvements in Biology Compared to Integrated Circuit Productivity.

Other potential metrics, such as molecular cloning, protein expression, protein purification, structure determination, and model building, also display exponential growth rates indicating that it is not simply specific applications, but rather the whole field of molecular biology which is advancing exponentially.<sup>3</sup>

#### The Backend: Standardized Kits, Automation, Low Cost Labware

The laboratory bench is undergoing a revolution due to the standardization of kits and protocols. Kits reduce cost, but more importantly allow experiments to be run by minimally skilled labor following a recipe. The reduction in required skill has enabled participation in biotechnology by many more people. Separately, automation has replaced PhDs and graduate students with robots. Overall, productivity in a wide variety of fundamental operations has been doubling roughly every 18 months for two decades.

Knowledge, alone, is insufficient to produce an explosion of activity if experiments remain expensive. The information technology (IT) revolution did not have widespread participation until computing had moved from expensive centralized mainframes to relatively cheap personal computers on the desktop. Biotechnology is on the cusp of the same revolution. The cost to outfit a small lab has now dropped below a few thousand dollars and indeed there are the beginnings of a biotechnology hobbyist movement in the United States akin to the early home computer movement.

<sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Carlson, "The Pace and Proliferation of Biological Technologies."

<sup>4</sup> Ibid.

Carlson, *Biology Is Technology*.

<sup>6</sup> Ledford, "Garage biotech: Life hackers."

#### **Economic Drivers**

Nuclear technology is expensive and the rewards for any nation undertaking a weapons program are not immediate. Iran, for example, has borne the expense of enrichment infrastructure, the cost of scientists on a multi-decade research program, and the burden of economic sanctions as weighed against eventual national prestige and functional weapons. By contrast, biotechnology programs are inexpensive and profitable and the more skilled one becomes the more products one can sell. Economic rationality, rather than politics, is drawing many nations, and individuals, to pursue biotechnology.

#### Big, Growing Markets

Biotechnology is often associated with just two markets: medicine and agriculture. Yet the influence of biology on society is pervasive and there are many more markets and many more dollars at stake. For example, the biofuels industry is concerned not just with liquid fuels and agricultural feedstock, but also with producing enzymes, metabolic pathways, and organisms that convert biomass to fuels. In the U.S., industrial biotech, in which biology replaces industrial processes in the manufacturing of the products of everyday life, is now larger than biotech medicine or agriculture and is growing roughly twice as fast.

Large markets are attractive not only to governments concerned with economic growth, but also to individuals. At all skill levels, jobs in biotechnology tend to pay considerably above national averages around the world. Biotech employment in the United States climbed at a greater than 10% annual rate between 1990 and 2010. Both China and India have identified biotech as a source of job and wealth creation, and are investing accordingly. The fifty member states of the Islamic Educational, Scientific, and Cultural Organization announced a strategy in 2003 that highlighted the economic benefits, and educational needs, of biotechnology in the Islamic World. \*

#### Structural Changes in the Marketplace

It is often said that greater efficiency is found in greater scale or, in other words, that economies of scale always favor large production facilities. This is true for many activities, for example steel making, where one large blast furnace is more efficient than a hundred smaller smelters. This is an assertion that China unwittingly tested during the Great Leap Forward of the 1950's when peasants were directed to create backyard smelters and promptly cut down 10% of China's trees for fuel in just a few months. Biology, however, rarely displays the same returns to scale as industrial processes and therefore does not require that companies be large in order to succeed. Thus the bioeconomic marketplace may not be dominated by a few large producers (who can be easily monitored). Instead, there may be numerous actors and a great diffusion of skills and knowledge. An example, which will be explored later in more depth, is that of microbrewers who compete successfully in a commodity market with the largest of multinationals.

A second change has been the maturation of the biology marketplace. Decades ago, to attempt a genetic experiment required a monolithic, vertically integrated, strategy. Producing a product based on a genetically modified organism required in-house expertise in a range of skills spanning biochemistry, molecular biology, and microbiology. Every one of these skills is now a service available for purchase. Specialization creates new niches where companies can thrive; it also facilitates proliferation. Today, it is

Carlson, Biology Is Technology.

<sup>&</sup>lt;sup>8</sup> ISESCO, "Strategy for Development of Biotechnology in the Islamic World."

<sup>&</sup>lt;sup>9</sup> Economy, The River Runs Black.

quite simple to find an interesting gene sequence in an online database, electronically submit this to a DNA foundry to be written, and have the resulting molecule shipped to a protein expression house for manufacture and delivery to your doorstep. Increased access does not necessarily improve the odds that a research project will be successful. Nonetheless, increased access enables individuals and small groups to engage in innovation—whatever their goals may be, wherever they choose to pursue them.

The proliferation of biological technologies is also altering the international web of economic ties, enabling developing nations to establish collaborations that have no connection to the United States or other developed economies. According to a recent survey of biotech firms in developing countries, one quarter of respondents were engaged in South-South (SS) collaborations—meaning collaborations between developing countries—and about half were engaged in North-South (NS) collaborations—meaning collaborations between a developed and a developing country. SS collaborations cover a wide array of scientific and economic activities, including distribution, Research and Development (R&D), training, clinical trials, providing materials, and contract research. The authors note that collaborations including an R&D component are somewhat less common between Southern countries than between Northern countries, which suggests that this number might serve as a metric for tracking economic progress in developing countries. The authors conclude that SS collaborations serve to amplify competitiveness both regionally and globally, and observe that almost all collaborations disclosed were initiated at the level of enterprise rather than of governments or international organizations. As expected, economic activity is driving a global proliferation of biotech skills and knowledge.

#### A Very Different Threat Landscape

Economic demand is driving proliferation, which suggests policy makers in the United States will have very different concerns going forward than those which have previously dominated the conversation. In addition to state-sponsored bioweapons programs, or efforts by terrorist groups that pose a physical threat, policy makers must now contend with state-guided biotechnology programs that pose an economic threat. Rather than identifying and tracking a few highly-educated microbiologists capable of running a fermentation or cell-culture facility, policy makers must contend with a global profusion of workers with varied educational backgrounds who can create new genetically modified organisms by following recipes that only involve measuring and mixing liquids from color coded tubes.

Speculation about the achievement of specific biotechnological capabilities on a 5 to 10 year horizon is of dubious utility. The technologies used to read and manipulate DNA have changed radically in just the last 5 years, let alone the last 10. Therefore, in the context of this report "threat" should be taken to mean the capability to cause harm or produce unwelcome surprises, or the capability to undermine U.S. economic or political interests, rather than the development and use of a specific agent or technology. This document follows the longer term definition of threat implied by the National Strategy . The National Strategy asserts that "risk is evolving in unpredictable ways", and that we "must take action to ensure that advances in the life sciences positively affect people of all nations while we reduce the risks posed by their misuse". A "threat", in this context, would therefore be an advance in the life sciences with negative effects or that increased the risk posed by misuse.

Gauging what constitutes a real threat will become increasingly difficult as economies around the globe come to rely more on biotechnology. Initially, it should be possible to monitor such metrics as revenues,

Thorsteinsdottir et al., "South-South entrepreneurial collaboration in health biotech."

<sup>11</sup> National Security Council, National Strategy for Countering Biological Threats.

investment, education, and employment in order to help evaluate the threat potential for various countries. However, wide-scale proliferation will make it very difficult to identify specific threats or specific individuals with particular skills. Moreover, as other countries become more sophisticated in their understanding of biotechnology and their planning for a bioeconomy, it will be natural for them to analyze the United States as a source of economic threats. In response, these countries may take actions which alter the U.S. perception of threats.

I begin the next section with a survey of the bioeconomy in the United States for three reasons. First, as data is most readily available for the United States it will serve as a benchmark for other countries. Second, I wish to provide some context for how the U.S. bioeconomy is viewed abroad. Finally, to assess potential threats over a timescale of 10 years one must first assess domestic skilled labor and markets.

#### **COUNTRY PROFILES**

In evaluating the economic potential of biotechnology I look at three factors: markets, labor, and government policy. The first factor is the absolute size of biotech markets and their composition (health care, agriculture, and industrial products). As a metric for this factor I calculate the Genetically Modified Domestic Product (GMDP), which is a country's gross revenue derived from biotechnology. A gauge for the second factor is the size of the skilled labor pool, and also its predicted growth. The final factor is government policy, and any special societal factors, which advance or retard proliferation.

#### **United States**

#### Bioeconomy

The United States presently generates more revenue from biotechnology than any other nation. As of 2008, U.S. revenues from genetically modified products were the equivalent of just under 2% of GDP and grew at 15–20% annually for the previous 5 years (Table 1). For comparison, in 2007 mining contributed 2% of U.S. GDP, construction, 4.1%, all of manufacturing 11.7%, and finance, 20.7%. <sup>12</sup>

Sector	Global Revenues (\$ billions)	U.S. Revenues (\$ billions)	% of U.S. GDP	Growth Rate of U.S. Revenues
Biotech drugs	82	70	0.5%	5%
Agbiotech/GMOs	~180	80	0.6%	9%
Industrial	~150	~95	0.7%	15%

Table 1. Estimates of U.S. and Worldwide Revenues from Genetically Modified Systems in 2008

Agricultural biotech, biofuels, and industrial revenues are surging. Second generation biofuels are scheduled to enter markets in Europe and South America in 2011, with many of the resulting dollars accruing to companies based in the United States. Biobased chemicals presently constitute about 5% of the U.S. market. Aggressive estimates from private consulting firms, the U.S. Department of Agriculture (USDA), and the U.S. International Trade Commission (USITC), suggest that by 2025 bioproduction could

<sup>&</sup>lt;sup>12</sup> U.S. Department of Commerce, Bureau of Economic Analysis, "Value Added by Industry as a Percentage of Gross Domestic Product."

provide 20–40% of the total worldwide chemicals market.<sup>13</sup> With rising crop prices and increased industrial biotech revenues, total U.S. biotech revenues could easily surpass 3% of GDP by 2015.

#### Labor

Approximately 250,000 people are employed in biotech in the United States. This workforce grew at an average of 10% annually for much of the last decade. In addition, the labor pool is bolstered every year by graduates with degrees in the biological sciences, distributed in 2006 as follows according to the National Science Foundation (NSF): 73,000 bachelors degrees; 8,700 masters degrees; 6,600 doctoral degrees. Based on NSF statistics, I estimate that two million university-level students in the last two decades have had the opportunity to acquire skills relevant to genetic modification. Moreover, high schools in the U.S. teach similar skills to an additional (roughly) 100,000 students annually. Adding up these numbers must substantially overestimate skilled biotech labor in the United States. However, if even 20% of the total actually learned how to manipulate DNA during their university or secondary education, then these graduates would exceed the number formally employed in industry and academia.

#### Government Policy

The U.S. government has no specific industrial policy promoting biotechnology. However, since the initial demonstration of recombinant DNA technology in the mid-1970's the field has been the recipient of hundreds of billions of federal, state, and private research and development funding. Currently, life sciences as a whole receive approximately \$30 billion a year in government R&D funding.<sup>18</sup>

One government-wide policy may preference products made using biological technologies. The USDA Biopreferred program "aims to increase the purchase and use of renewable, environmentally friendly biobased products" by all branches of the federal government. Specific biotech sectors also enjoy supportive government policies. At the federal level, biofuels (ethanol and biodiesel) have seen a producer excise or income tax credit for each gallon of fuel produced. In addition 14 states have minimum blending requirements which require a percentage of biofuels in the fuel mix sold to consumers. However, there are very few, if any, direct incentives for the industrial biotechnology sector for products such as biobased chemicals or bioplastics.

Office of the Chief Economist, Office of Energy Policy and New Uses, U.S. Department of Agriculture, U.S. Biobased Products: Market Potential and Projections Through 2025; Biotechnology Industry Organization, "Biobased Chemicals and Products: A NEW DRIVER OF U.S. ECONOMIC DEVELOPMENT AND GREEN JOBS."

<sup>&</sup>lt;sup>14</sup> Carlson, *Biology Is Technology*.

Office of the Chief Economist, Office of Energy Policy and New Uses, U.S. Department of Agriculture, U.S. Biobased Products: Market Potential and Projections Through 2025.

<sup>&</sup>lt;sup>16</sup> National Science Foundation, "S&E Degrees: 1966–2006: Detailed Statistical Tables."

<sup>&</sup>lt;sup>17</sup> Cachianes, "Personal Communication."

<sup>&</sup>lt;sup>18</sup> National Science Board, "Key Science and Engineering Indicators: 2010 Digest."

<sup>&</sup>lt;sup>19</sup> U.S. Department of Agriculture, "BioPreferred Program."

<sup>&</sup>lt;sup>20</sup> U.S. Department of Energy, "Alternative Fuels and Advanced Vehicles Data Center: Federal Incentives and Laws."

<sup>&</sup>lt;sup>21</sup> U.S. Department of Energy, "Alternative Fuels and Advanced Vehicles Data Center: All Incentives and Laws Sorted by Regulation."

#### **Pakistan**

#### Bioeconomy

Pakistan is still developing from an agrarian past, and its economy remains overweighted in the agricultural sector. Sectoral contributions to GDP in 2009 from agriculture, industry, and services were 21.8%, 24.3%, and 53.8% respectively." The GMDP of Pakistan is roughly 1.6% of GDP and is due almost entirely to GM crops, with unmeasurable contributions from either biotech drugs or industrial biotech.

With agriculture contributing over a fifth of GDP, Pakistan has a strong incentive to adopt biotechnology and increase yields. Additional motivations include increasing food security and ameliorating Pakistan's balance of payments problem. (Pakistan narrowly avoided insolvency in late 2008 only by accepting International Monetary Fund (IMF) aid, which has now grown to \$11.3 billion USD over 25 months.<sup>23</sup>) In total, 55% of Pakistan's export earnings are linked to cotton and textiles.<sup>24</sup> Perhaps the strongest motivation, particularly for national stability, is that 45% of the workforce is employed in agriculture and their economic betterment depends on higher yields.<sup>25</sup>

Despite substantial rationale, GM crops have not made inroads into Pakistan with one exception. Penetration has been slow for any number of reasons. Legal barriers of various sorts have long existed. The planting of GM seed became legal for the first time in 2010, and even then was restricted to nine cultivars of cotton, neglecting other crops such as rice, wheat, and soybeans. Pakistan has yet to pass legislation protecting the intellectual property of plant breeders, which has made multinational seed companies reluctant to do business there. An economic barrier has been the higher upfront cost of GM seeds, which, although paid back in higher yields, has reduced planting by poorer farmers.

The notable exception, which illustrates how economically driven bioproliferation can occur, is cotton. Although illegal, farmers smuggled Bt Cotton seed into the country for their own use. In 2002 seed was smuggled in hand luggage from Australia to Pakistan<sup>26</sup> and reported smuggling goes back to at least 1998.<sup>27</sup> A black market rapidly developed for GM seed. As of August, 2010, the USDA Foreign Agricultural Service estimates that GM varieties now account for practically 100% of the cotton acreage in Pakistan.<sup>28</sup>

The Pakistani pharmaceutical industry concentrates on the manufacturing of existing drugs rather than developing new ones. It is instructive to look at one company, BF Biosciences, which bills itself as Pakistan's first biological drug maker. The company produces off-patent biologics (see glossary) domestically. The logistical difficulties in starting up illustrate the serious in-country barriers to proliferation. In the United States, barriers to entry have been falling thanks to developments like an extensive used labware market. Just the opposite infrastructure situation exists in Pakistan. It took 2 years, for example, before BF Biosciences could secure electric power for their laboratory. During that time they had to rely on diesel generators. When they tried to acquire lab equipment, deliveries were

Pakistan Federal Bureau of Statistics, "Sectoral Shares in Gross Domestic Product (Real) 1999-2000 to 2008-09."

<sup>&</sup>lt;sup>23</sup> International Monetary Fund, "IMF Program Note: Pakistan."

<sup>&</sup>lt;sup>24</sup> Shafiq-Ur-Rehman, Pakistan: Cotton and Products Annual.

<sup>&</sup>lt;sup>25</sup> Pakistan Federal Bureau of Statistics, "PERCENTAGE DISTRIBUTION OF EMPLYED PERSONS 10 YEARS OF AGE AND OVER BY MAJOR SECTORS OF EMPLOYMENT, SEX, AREA PROVINCE AND PAKISTAN 2008-09."

<sup>&</sup>lt;sup>26</sup> Iqbal, "Pakistan opens doors to GM seed."

<sup>&</sup>lt;sup>27</sup> Shafiq-Ur-Rehman, Pakistan: Cotton and Products Annual.

<sup>&</sup>lt;sup>28</sup> Shafiq-Ur-Rehman, Pakistan: Biotechnology - GE Plants and Animals Annual.

held in Shanghai for 8 months, a delay that the chief executive officer attributes to an assumption that someone in Pakistan could only want such equipment for malign purposes.<sup>29</sup>

An additional note is that BF Biosciences still needed participation of outside parties to get the plant operating. This speaks to the lack of a sufficiently skilled labor pool. The partner they chose was Bago Laboratories of Argentina.<sup>30</sup> As more nations and regions acquire biotech knowledge, the flows of skills are increasingly likely to bypass the United States as in this "South-South" knowledge transfer.

#### Labor

The biotech profession is too new and too small to appear in official Pakistani government statistics. While the current skilled labor pool is small, the expected growth rate is large. Pakistan has been investing heavily in education. It more than quadrupled overall education budgets from 2001 to 2006<sup>31</sup> and has set up 27 institutes with specific biotechnology education programs.<sup>32</sup> Yet the prospect of widespread diffusion of biotech skills into unconventional settings seems remote. General education is still not widespread; the literacy rate for Pakistan is just 57%.<sup>33</sup> The latest educational census from 2005 shows that just 10,249 students (2.2% of majors) were seeking a degree in biology across all degree levels.<sup>34</sup> Not one student in the entire country was pursuing postgraduate work in biology in 2005.<sup>35</sup>

#### **Government Policy**

The government takes an active role in promoting biotechnology. In the sciences as a whole, policy and funding together have produced a remarkable increase in Pakistani R&D Intensity (see glossary) which more than doubled in the decade to 2007. The government invested about \$25 million in biotech in the fiscal year 2008–09 alone.

The government has, for many years, identified biotechnology as a major national priority in science. We are at the stage now in Pakistan where we have done enough research in the lab and we are now ready to scale up and commercialize.

— Anwar Nasim, President of the Federation of Asian Biotech Associations and chairman of Pakistan's National Commission on Biotechnology<sup>38</sup>

The National Institute for Biotechnology and Genetic Engineering was established by, and remains a division of, the Pakistan Atomic Energy Commission. The Atomic Energy Commission has proven experience in developing and managing the scientific, technical, and economic aspects of large research projects. In other words, the biotechnology and genetic engineering program is being managed by a bureaucracy that within a relatively short time developed and tested Pakistan's nuclear weapons.

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<sup>&</sup>lt;sup>29</sup> Inman, "Battling To Build A Biotech."

<sup>30</sup> Wasif, "Argentina wants to set up biotechnology industry in Pakistan."

<sup>31</sup> Hayward, "Higher Education Transformation in Pakistan: Political and Economic Instability."

<sup>32 &</sup>quot;Institutes of Biotechnology in Pakistan."

<sup>33</sup> Pakistan Federal Bureau of Statistics, "PERCENTAGE DISTRIBUTION OF POPULATION BY AGE, SEX LITRACY AND LEVEL OF EDUCATION 2008-09."

<sup>&</sup>lt;sup>34</sup> Higher Education Commission Pakistan, "Discipline wise Enrollment during 2004-05 (provisional)."

<sup>35</sup> Ibid.

<sup>&</sup>lt;sup>36</sup> UNESCO, Institute for Statistics, A GLOBAL PERSPECTIVE ON RESEARCH AND DEVELOPMENT.

<sup>&</sup>lt;sup>37</sup> Aldridge, "Pakistan's first biotech plant."

<sup>38</sup> Ibid.

In 2001 the government of Pakistan set up a National Commission on Biotechnology as an advisory body to the Ministry of Science and Technology. The Commission has duly gone on to make recommendations and there have been some successes such as the establishment of several national institutes specializing in biotechnology. These institutes have been able to develop indigenous varieties of several GM seeds.

While there has been some progress in Pakistan, it is useful to compare the country with Malaysia. Malaysia did not have a biotechnology strategy until 2005, 4 years after Pakistan. In 2005, the government of Malaysia highlighted the strategic importance of biotechnology by devoting a full chapter to it in the Ninth Malaysia Plan (2005–2009). The government began by quadrupling investment in the area. These funds were directed not only to education (human capital), but also to facilities and equipment and entrepreneurship. Unlike Pakistan, which has mostly opted for a centralized, government-run effort, Malaysia has chosen a public–private model. While investing in areas such as education, traditionally a public effort, it has also offered many financial incentives to attract companies to Malaysia. Consequently, in 2010, there were 163 companies operating in Malaysia under the BioNexus program.<sup>39</sup> Moreover, Islamic Malaysia has identified and begun developing a new market for halal biotech products; a market that no Western biotechnology company had foreseen. When compared with Malaysia it is clear the Pakistani government's efforts have been positive, but not nearly as effective as those of other developing countries.

#### India

#### Bioeconomy

India is enjoying a booming bioeconomy. Biotech revenues have risen rapidly in recent years, from less than \$1 billion in 2004, to \$2 billion in 2006, with an industry expectation of \$5 billion in 2010. Biologics dominated 2009 biotech revenues, with 65% of total revenues, followed by bioservices (contract research) at 17% and GM crops at just over 12% (see Table 2). While acreage has stayed constant, Bt Cotton is now grown on at least 90% of fields, which was a significant factor in doubling cotton yields between 2002 and 2007. Exports reportedly accounted for 60% of total biotech revenues in 2009. India's Department of Biotechnology is forecasting sales of up to \$25 billion by 2015. Yet despite the rapid historical and forecast growth of Indian biotech, the industry is relatively new, generating only 0.2% of GDP in 2009.

<sup>39</sup> Malaysian Biotechnology Corporation, "10TH MP UNDERSCORE BIOTECHNOLOGY AS EMERGING CONTRIBUTOR TO GDP."

<sup>40</sup> Ramachandran, "India's blossoming biotech boom."

<sup>41</sup> Rao, "Growth Slows."

<sup>42</sup> Suresh, "Today's biotech industry in India."

<sup>43</sup> Rao, "Growth Slows."

<sup>44</sup> Ramachandran, "India's blossoming biotech boom."

Segment	Revenues (Rs billions)	Revenues (\$ billions)	Growth (%)
Biopharma	7,883	1.7	14
Bioservices	2,062	0.44	31
Bioinformatics	220	0.05	16
Bioagriculture	1,494	0.32	24
Bioindustrial	478	0.1	17
Total	12,137	2.6	18

**Table 2**. 2009 Indian Biotech Revenues. 45 1 USD = 46 INR.

The Indian biotech sector is heavily dominated by pharmaceuticals and contract research, with industrial biotech contributing only about 4% of total revenues. Within biopharma, Indian firms have been very successful in penetrating international markets by reducing production costs. For example, Shantha Biotechnics produces a hepatitis B vaccine that costs only \$1.25 per dose—just 1% of the cost of the vaccine previously on the market—and now supplies 40% of the hepatitis B vaccine provided by the United Nations Children's Fund. This sort of radical price shift could be repeated, producing discontinuous change in the current marketplace and destroying Western preeminence in the industry.

#### Labor

As the biotech sector is new, there are no readily available estimates of the size of the workforce. The composition of the labor pool, however, is ill-suited to current conditions. A recent preliminary assessment in Nature Biotechnology of the biotech workforce in India described an up-and-coming industry that is beset by a critical lack of specialized skills. Prior to 2000, Indian companies focused on vaccines and generic small molecule drugs. As a result, new biotech ventures tend to hire expertise from abroad for key scientific and executive positions. Moreover, while there are sufficiently skilled cell biologists in academia and government institutions, those skills have evidently not been transferred to industry. The expertise required to design cell-based assays is described as "rare" in industry, which means that a crucial engineering technology required to test the function of new compounds and pathways is also rare. Ongoing investment in education will eventually address these issues, but the combination of a small skilled workforce and a relatively small industrial revenue base suggest that it will be some years before India's biotech sector is adequately staffed.

#### Government Policy

The rapid growth in commercial biotech activity is supported by substantial public sector coordination and spending. The Government of India sees biotechnology as an important future component of its economy. The most recent Annual Report from the Department of Biotechnology, within the Ministry of Science and Technology, describes an ambitious effort to increase the training and support of students and researchers at all levels. The country is reportedly now graduating 20,000 university level biotech students annually, which is the equivalent of about 10% of the entire—and substantially larger—U.S.

<sup>45</sup> Rao, "Growth Slows."

<sup>&</sup>lt;sup>46</sup> Ramachandran, "India's blossoming biotech boom."

<sup>&</sup>lt;sup>47</sup> Saberwal, "Seeding a skilled workforce."

<sup>48</sup> Ibid

<sup>&</sup>lt;sup>49</sup> Department of Biotechnology, Ministry of Science & Technology, "Annual Report 2009-2010."

biotech workforce. Moreover, the report catalogs impressive achievements in domestic instrumentation and technology development, as well as the development of a wide variety of genetically modified crops and biological methods for pest control and soil maintenance.

The National Biotechnology Development Strategy, first published in 2007, declares that 30% of the Department of Biotechnology's budget be spent on public–private partnerships. These partnerships are explicitly aimed at product development, in essence a government-funded commercialization program, "with a focus on contributing to a long-term and sustainable bioeconomy." The budget for the Department of Biotechnology during the eleventh 5-year plan is 4 times larger than its budget in the previous cycle. The budget in the previous cycle.

#### China

#### **Bioeconomy**

Biotechnology is nothing new in China. A smallpox vaccine was in use in China in the 14th century<sup>54</sup>, and the country has a history of fermentation that goes back at least 9,000 years.<sup>55</sup> Building upon these millennia of experience, the country has turned aggressively to biotechnology over the last decade. Various sources put the total 2007 revenues in China from biotechnology at more than \$117 billion out of a total GDP of about \$4 trillion.<sup>56</sup> Thus biotech revenues have already exceeded 2.5% of GDP. In 2006, 60% of China's biotech revenues reportedly came from biologics, 36% from food and agriculture, and 2.5% from industrial applications.<sup>57</sup> A different report put China's 2007 industrial biotech revenues at a substantially larger \$60.5 billion.<sup>56</sup> The Chinese government expects biotech revenues to reach 5% of GDP by 2020; a private consulting firm expects these revenues to actually be in the range of 7–8% of GDP.<sup>56</sup> Given the expected annual growth rate in Chinese GDP, deriving 8% of GDP from biotech would require a more than tenfold increase in absolute biotech revenues in 10 years.

Within the subsectors of GMDP, the biopharmaceutical sector experienced a 20–30% annual growth rate in the years between 2000 and 2010. Agricultural biotech revenues will also expand rapidly as China currently only plants 5% as much land in GM crops as the United States, and this is acreage is dominated by insect resistant cotton. The USDA lists 10 varieties of rice, papaya, soybeans, tomato, pepper, poplar, and cotton as in "commercial development" in China, although only the latter two have been widely

<sup>50</sup> Suresh, "Today's biotech industry in India."

<sup>51</sup> Department of Biotechnology, Ministry of Science & Technology, "National Biotechnology Development Strategy."

<sup>52</sup> Ibid

<sup>&</sup>lt;sup>53</sup> Ibid.

Dean H. Hamer and Shain-dow Kung, Editors; Committee on Scholarly Communication with the People's Republic of China, National Academy of Sciences, *Biotechnology in China*.

<sup>55</sup> McGovern et al., "Fermented beverages of pre- and proto-historic China."

Nesbitt, "Industrial Biotechnology in China Amidst Changing Market Conditions"; International Technology Transfer Center, "Gross output value of China biotechnology industry achieved 800 billion RMB Yuan in 2008."

<sup>&</sup>lt;sup>57</sup> clearstate, "China's biotech Long March."

<sup>&</sup>lt;sup>58</sup> Nesbitt, "Industrial Biotechnology in China Amidst Changing Market Conditions."

<sup>&</sup>lt;sup>59</sup> Xinhua, "Scientist: biotechnology to account for 5 percent of China's GDP in 2020"; clearstate, "China's biotech Long March."

<sup>60</sup> Carlson, "The Pace and Proliferation of Biological Technologies."

Marshall, "13.3 million farmers cultivate GM crops"; Brookes and Barfoot, "GM crops: global socio-economic and environmental impacts 1996-2006."

planted thus far. The government has approved field trials of genetically modified corn and rice, with ongoing research into soybeans and rapeseed.

In addition to a blossoming domestic biotech industry, many Western biotech companies have opened research and development centers in China over the last decade, in part to take advantage of costs for skilled labor that are as low as one-fifth those in the United States and Europe. Investing in Chinese biotech labor, and the attendant technology transfer, may initially be intended to support a less expensive drug development effort. Yet that labor will inevitably serve as a resource for competitive efforts emerging from within China, recapitulating the course of other fields, from telecommunications, to aviation, to high speed rail.

China currently supplies 75% of the pharmaceutical ingredients used in the United States<sup>®</sup>, many of which are produced using industrial biotechnology.<sup>®</sup> It would be surprising if the country did not attempt to capture more value by moving to manufacture drugs domestically for an export market. This will require developing a local skill base that is conversant in everything from fermentation (in which they already excel) to the engineering of complex genetic circuits. While there may presently be a local deficit in the requisite skill base, in addition to permanently luring "sea turtles" (see glossary) home from overseas, there are an increasing number of "seagulls" (see glossary) who transit multiple times between China, the United States, and Europe, maintaining collaborations around the world and serving as conduits for knowledge.<sup>®</sup>

#### Labor

The current absolute size of the biotech labor pool in China is unknown. However, a recent article from Nature Biotechnology suggests that while the country may be producing many graduates in areas related to biotechnology, they are not trained in a way useful to industry. Most hires in U.S. biotech companies come from other companies, but in China the supply of skilled labor is still so small that most hires are fresh out of university. On-the-job training requires an additional 1–3 months to provide workers with relevant skills.

Given China's performance in other areas over the last two decades, it would be unwise to assume it will fail to address its labor shortfalls in biotech. The national scientific establishment is already attempting to lure back foreign-trained Chinese scientists by offering lucrative financial packages. Still, the Chinese government has previously made missteps in centrally planning education. To wit, this interesting recent excerpt from China Daily:

Chinese universities usually decide the number of places for each major and then recruit students to fill them based on their university entrance exam scores, rather than letting students choose majors.

...Another reason college graduates have struggled to find work is that there are simply too many of them - a legacy of the government's efforts in 1999 to simultaneously improve the quality of the

<sup>&</sup>lt;sup>62</sup> Petry and Bugang, China: Biotechnology; Petry and Rohm, China Moves Forward in New Technologies.

<sup>63</sup> Weixiao, "China signals major shift into GM crops."

<sup>64</sup> May, "Of Sea Turtles And Seagulls."

<sup>&</sup>lt;sup>65</sup> Zhang and Deng, "Enforcing pharmaceutical and biotech patent rights in China."

<sup>66</sup> Nesbitt, "Industrial Biotechnology in China Amidst Changing Market Conditions."

<sup>67</sup> May, "Of Sea Turtles And Seagulls."

<sup>68</sup> Breithaupt, "China's leap forward in biotechnology."

<sup>69</sup> Chinoy and Xiaotian, "Workers falling through skills gap."

workforce and fight unemployment by dramatically expanding the country's higher education system. That year, college enrollment was increased by about 47 percent to 1.6 million students. The result, however, was not quite what was intended: a huge increase in the number of graduates that the Chinese economy remains unable to absorb to this day.

During the late 1990s, the government mandated an increase in engineering enrollment, which successfully produced so many engineers that pay fell substantially, leading to master's level graduates being hired for the same salaries that had once been paid to bachelor's level graduates. As of 2006, the combination of oversupply and a constriction of the job market meant that, across all disciplines, approximately 60% of graduates were unable to find work in their area of specialization, with 30% of engineering graduates unable to find any work.

As will be discussed later, due to the oversupply of labor, engineering and computer science graduates in China have found employment in areas other than those favored by the government. The same fate may await any mass of skilled biotech labor resulting from a directive by the central government.

#### **Government Policy**

Premier Wen Jiabao, in a 2006 speech describing "The National Program 2006–2020 for the Development of Science and Technology in the Medium and Long Term", set key goals of increasing R&D expenditure to 2.5% of GDP (nearly doubling the 2006 rate) and quadrupling the 2000 GDP by 2020. In the 10 years up to 2007, China increased its gross expenditures on R&D by a factor of 6; the number of scientists and engineers engaged in R&D increased by a factor of 3 to almost 1.5 million; and graduate student enrollment increased by a factor of 6 to just under 1.2 million.

China is investing heavily in biotechnology as part of a long-term development program. This program is expected to reshape all aspects of Chinese society and economy. In 2002, President Jiang Zemin stated publicly that the government would use all means available to improve the health of the population, including genetic modification of its citizens. In September of 2008, a new plan was announced governing R&D investment in which 30% of all funds were directed to biotechnology. During the announcement of the plan Premier Wen Jiabao stated, "To solve the food problem, we have to rely on big science and technology measures, rely on biotechnology, rely on [genetic modification]." The "food problem" to which the Premier referred is a combination of a still-increasing population and a recent, precipitous decrease in arable land.

Besides setting targets and directing government research investments, Chinese industrial policy also seeks preferences for locally owned companies. The Indigenous Innovation Products Accreditation Program requires that the government procure products only from companies that own their own intellectual property, thus excluding from government procurement any multinational company or local subsidiary with mere licensing rights."

<sup>72</sup> Schwaag Serger and Breidne, "China's Fifteen-Year Plan for Science and Technology: An Assessment."

<sup>&</sup>lt;sup>70</sup> Gereffi et al., "Getting the Numbers Right."

<sup>&</sup>lt;sup>/1</sup> Ibid

<sup>&</sup>lt;sup>73</sup> Cao, Simon, and Suttmeier, "China's innovation challenge."

<sup>&</sup>lt;sup>74</sup> Epstein, Global evolution of dual-use biotechnology; Cantor, "Global evolution of dual-use biotechnology: 2020."

<sup>75</sup> Stone, "PLANT SCIENCE: China Plans \$3.5 Billion GM Crops Initiative."

<sup>&</sup>lt;sup>76</sup> Xin et al., "Review of Arable Land-use Problems in Present-day China."

<sup>&</sup>lt;sup>77</sup> Gwynne, "The China Question."

Finally, China is reaching out to other developing countries through economic and scientific ties. A government institute, the Beijing Pharma and Biotech Center, aids Chinese biotech companies in setting up operations around the world, with the explicit aim of training foreign labor. These efforts result in both a local skilled workforce and the production of valuable health care products. For example, one collaboration involved transfer of technology from a Chinese company to an Egyptian company, culminating in a domestic Egyptian capability to produce recombinant insulin. As a consequence, Egypt is now self-sufficient in insulin production.

#### IMPLICATIONS AND DISCUSSION

#### **Economic Fundamentals and the Potential for Surprise**

With exponential improvements in capability and millions of potential independent actors, biotech surprises are guaranteed. By "surprise", I mean the development of a technology or capability by a particular actor that could not be easily foreseen by tracking the prior development of that actor and that may pose a risk to U.S. interests. Producing a surprise will require skills, information, and a sufficient infrastructure, and developing metrics to assess progress in these areas will facilitate gauging the potential for surprise. Toward this end, Table 3 collects estimates of selected national and regional 2010 biotech revenues as a percentage of GDP, estimated revenue growth, and, if applicable, national government future revenue targets. This paper was limited in scope, and it is likely that other countries have equally strong biotech sectors.

Country	2010 Biotech Revenues	2010 Est. Growth	2020 Target Biotech Revenues
Malaysia	2.5%	25%	10%
China	2.5%	20%	5–8%
United States	2%	10–15%	NA
India	0.2-0.4%	20%	1.6% (2015)
Pakistan	1.6%	<5%	NA
Europe	<1.0%	5%	NA

Table 3. Biotech Revenues as Share of GDP

The main source of uncertainty is the definition of "biotech". (See also Appendix A.)

Comparing Malaysia and Pakistan provides an interesting contrast regarding surprise potential. In Pakistan, government institutes and government-funded academics have made progress in developing new genetically modified crops and bioindustrial processes. However, the overall educational state of the country and the lack of ready investment make it unlikely that Pakistan will see much economically-driven proliferation of biotech for many years to come. Pakistan's domestic biopharmaceutical industry may finally begin producing revenues only in mid- to late-2011, and even that progress was due to external involvement and investment from Argentina. In summary, it would be surprising for something surprising to emerge from Pakistan without a substantial change in fundamental enabling trends such as the literacy rate, secondary school graduation rates, and foreign direct investment.

<sup>&</sup>lt;sup>78</sup> Stone Fish, "Building Biotechnology In Beijing."

<sup>79</sup> Thorsteinsdottir et al., "South-South entrepreneurial collaboration in health biotech."

By contrast, it was a surprise to discover during the research phase of this project the extent to which Malaysia, which was not included in the original scope of research, has developed a thriving bioeconomy. The relevant timescale for this transformation was just 4 years. As a result, policy makers concerned specifically about a proliferation of biotech skills in countries home to Islamic extremists should note that individuals can now choose from many different countries in which to acquire skills. Travel between the Middle East and Southeast Asia, for example, is quite common and will not necessarily be obvious to the U.S. intelligence community. Economically-driven proliferation in Malaysia may provide the opportunity to study or work in a booming biotech sector to a citizen of a country in which the bioeconomy may be lagging. That citizen might subsequently return home to practice those skills. Therefore, surprises may arise in a country of concern due to skills acquired elsewhere.

Over the last decade India has moved from limited investment and support of biotechnology to aggressively pursuing the economic benefits of the industry. Exports reportedly already account for 60% of India's biotech revenues. Yet the sector produces only a very small fraction of India's GDP, and at present can only employ a small number of skilled workers. The continued supply of skilled workers will determine whether the sector can maintain its torrid pace of growth. Nonetheless, as companies within India have moved into manufacturing vaccines and biogenerics, Western companies have seen their revenues slashed in short order. This sort of near-discontinuous price change is a feature of Indian innovation and must be considered as a threat to the economic survival of U.S.-based (higher fixed costs, longer R&D budget cycles) biotech firms.

China also produces materials and biotech drugs that compete with Western products. Moreover, it is developing trade and joint research networks in many developing countries. China is already a supplier of biotech reagents and instrumentation throughout Asia, Latin America, the Middle East, and Africa. Given the rapid increase in biotech investment and the presence of education quotas in China, it is likely that these trends will accelerate. This is the stated goal of the Chinese leadership; on January 9, 2006, Premier Wen Jiabao announced a plan to "catch up with the most advanced nations in biotechnology" while strengthening "independent" or "indigenous" innovation.<sup>51</sup>

The use of biological technologies has spread widely throughout China. The 2005 Renewable Energy Law committed the country to extending the successful "rural energy zoology model" for producing biogas for home heating and cooking using anaerobic digesters. By 2008, total capacity included at least 26.5 million households. In other words, much of the population of China is already familiar with distributed biological production systems that are entirely the product of indigenous innovation.

It is from the emergence of indigenous innovation that the most surprising results will unfold. One way to understand what may happen is to review a sector of the U.S. economy that has already been refashioned by a proliferation of participants with new ideas.

#### Microbrewing the Bioeconomy

Fermentation is an example of a widely distributed biological technology used to produce everything from laundry enzymes, to vitamins, to beer. The evolution of brewing economics and technology in the United States provide an example of meeting market needs via distributed biological manufacturing.

<sup>80</sup> Rao, "Growth Slows."

<sup>81</sup> Schwaag Serger and Breidne, "China's Fifteen-Year Plan for Science and Technology: An Assessment."

<sup>&</sup>lt;sup>82</sup> Runqing, Juneng, and Zhongying, "China's renewable energy law and biomass energy."

<sup>&</sup>lt;sup>83</sup> Chen et al., "Household biogas use in rural China."

Before Prohibition, the vast majority of beer produced in the United States was brewed by relatively small operations and distributed locally. Refrigeration was uncommon, and there were as yet no highways and motorized trucks, so beer had to be consumed rather than produced and stored in large quantities. During the years 1920–1933, the official count of breweries was forced to zero by government policy and enforcement.

After Prohibition, brewing was regulated and small-scale producers were legally shut out of the market. But with the aid of refrigeration and transportation, large-scale breweries proliferated. Consolidation inevitably took its toll and the number of breweries in the United States shrank until about 1980. In 1979, the passage of the Cranston Act allowed individuals to brew 100 gallons a year for personal use. Contemporaneous changes to federal and state excise taxes enabled those individuals to sell their beer, thereby reopening the market to small brewers. Deregulation reopened the market to craft brewers and the industry blossomed through organic growth and the preferences of consumers.

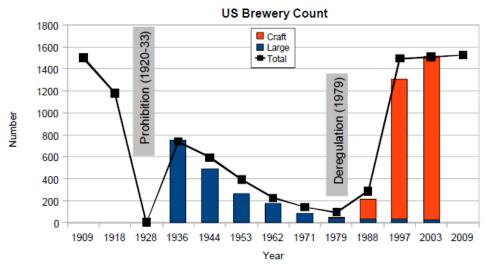


Figure 2. U.S. Brewery Census Data<sup>85</sup>

The growth in the United States of a new industrial sector shows that small-scale, distributed production can compete against an installed large-scale infrastructure base. By 1997 there remained just three major labels in the United States, with about 1,500 craft brewers (See Figure 2).

#### Economic Opportunity Bred A Proliferation of Skilled Labor

That home brewing had been almost nonexistent prior to 1979 points to another interesting feature of the market; namely, that the skill base for brewing was quite limited. Thus another effect of legalizing home brewing was that people could practice and build up their skills; they could try out new recipes and explore new business models. While craft brewers provide only 4.3% of the volume of beer sold in the United States, they take home 6.9% of the revenues, demonstrating that entrepreneurs can use biological production to succeed economically against existing large companies and to command a premium even in a commodity marketplace.<sup>50</sup>

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<sup>&</sup>lt;sup>84</sup> Tremblay, Iwasaki, and Tremblay, "The Dynamics of Industry Concentration for U.S. Micro and Macro Brewers."

<sup>85</sup> Tremblay, Iwasaki, and Tremblay, "The Dynamics of Industry Concentration for U.S. Micro and Macro Brewers"; Brewers Association, "Brewers Association | Facts."

<sup>86</sup> Brewers Association, "Brewers Association | Facts."

As a culture of innovation, the craft brewing movement is no stranger to technology development. Homebrewers are now incorporating into their projects the fruits of the open source hardware and software communities. For example, the Brewtroller Project is an "open source community focused on developing and supporting control systems for brewing beer". The hardware is based on the open source Arduino microcontroller and the associated community makes available schematics, parts lists, process code, and recipes. Notably, the goal of the software portion of the project is a program that "will walk through a series of stages (some optional) such as filling, preheat, dough-in, protein rest, acid rest, saccharifaction rest, mash out, sparge, boil and chill." This is a complicated process which is presently directed toward producing the perfect pint; but the Brewtroller is, in principle, complex enough to grow a wide variety of organisms and to produce a wide variety of substances. The Brewtroller also reduces the skill level required to employ fermentation as a technology, thereby enabling a greater number of individuals to brew beer, or perhaps to produce recombinant proteins.

The proliferation of distributed biological manufacturing that followed the legalization of craft brewing in the United States provides two lessons relevant to the present paper. First, it is clear that, given access to tools and skills, entrepreneurs can innovate and change markets even when those markets are dominated by large players; in other words, entrepreneurs can be a source of surprises. It would be prudent to consider this not simply a lesson about commercial competition, but also about nations. Second, while the rate of transformation demonstrated by China and India can be impressive, the timescale over which these countries are becoming internationally important in biotech is measured in units more similar to 10 years than 10 months. Even the transformation of the U.S. brewing industry required more than a decade, with the largest change coming in the latter years (See Figure 2).

The availability of skilled labor will be crucial in any bioeconomic transformation. Yet availability is changing on a daily basis with access to information available via the Internet, training that accompanies foreign investment by China and other countries, and access to equipment from an increasing number of suppliers around the world. The developing labor pool will be put to use in different ways around the world depending on the quality of the job supply. The situation emerging in biotech is likely to be similar to that experienced by the IT world over the last decade.

#### The Glocalization of Hacking Cultures

The proliferation of skilled computer programmers has overwhelmed the job supply in many countries. This imbalance may come about because of a labor oversupply or because local economic conditions produce a contraction of the job market. As a result, that skilled labor may look outside of the "legitimate" job market for work. According to a 2008 report from the IT security firm McAfee, in China today it is often easier to find a job writing malware than writing more socially acceptable code. There are many descriptions on the Web of programmers driven to employment as "black hat" (see glossary) hackers in countries such as Brazil, Russia, and Romania because no other option exists.

Local hacker communities often take on characteristics defined by local culture or market opportunities representing a "glocalization" (see glossary), i.e., the realization of a global phenomenon according to

<sup>87 &</sup>quot;BrewTroller."

<sup>&</sup>lt;sup>88</sup> Parekh, "BrewTroller - Brewing Control System."

<sup>&</sup>lt;sup>89</sup> Ong and Lin, "China: Painting the Threat Landscape."

<sup>&</sup>lt;sup>90</sup> Gilman, "Hacking goes pro."

local conditions. For example, 419 scams emerged locally in Nigeria in part due to the combination of English language education and access to international phone lines and then the Internet.

Unburdened by social and legal constraints common in the West, China's trailblazing scientists are also pushing the limits of ethics and principle as they create a new—and to many, worrisome—Wild West in the Far East.

—The Washington Post<sup>91</sup>

Certain countries may be more likely to develop biohacker cultures than others. The only obvious biohacker culture present in any country is in the United States, and even here it is nascent and probably composed primarily of individuals with innocuous intent. There are also signs of interest in building garage labs or bio-hackerspaces in other countries. It is not a great stretch to suggest that one likely consequence of proliferating skills and the rise of regional and global collaboration networks is the emergence of indigenous biohacker cultures. These cultures may arise around particular local problems or market opportunities, influenced by a wide range of government tolerance to, or even encouragement for, unconventional innovation. It is important to recognize that the emergence of such activity by itself need not be a threat, and in most cases will simply follow the natural course of innovation in small organizations. Nonetheless, as the supply of biotech labor saturates around the world, it would behoove the U.S. intelligence community to keep an eye on the potential emergence of indigenous "black hat" biohacker cultures.

#### **Necessity is the Mother of Invention**

Another economic driver of local innovation is the difficulty faced by international researchers in obtaining reagents and equipment from developed countries. For example, the first published global map of commercial DNA and gene synthesis suppliers carried the caveat that the open source search was carried out in English, which may have limited the search results. In fact, the map shows a lack of commercial DNA foundries in Central and South America because, surprisingly, there are no such businesses operating there. All orders for synthetic DNA originating in Central and South America are supplied from Europe, the United States, or China. Moreover, most reagents used in molecular biology are also internationally shipped to these regions. One consequence of this arrangement is that obtaining reagents (typically frozen, with limited shipping lifetime) is often hampered by delay or disappearance at Customs facilities. This state of affairs is surprising as (1) it represents a clear business opportunity for one or more domestic entrepreneurs to supply reagents in a timely fashion, and (2) it constitutes a driver for developing indigenous work-arounds that eliminate international orders.

#### **Regulations Built on Shifting Sands**

Another driver of indigenous innovation abroad would arise from restrictions on technologies currently supplied by U.S. companies. It is critical to note that restricting access to raw materials and markets has had very clear negative consequences in other markets, such as that for illegal drugs. In the case of methamphetamine, the U.S. Drug Enforcement Administration's own reporting reveals that suppression of local "mom-and-pop" production has resulted in foreign manufacture that surpasses the domestic

<sup>&</sup>lt;sup>91</sup> Pomfret, "China pushing the envelope on science, and sometimes ethics."

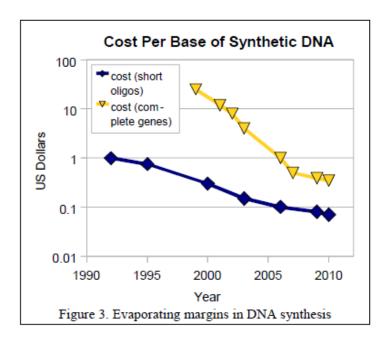
<sup>92</sup> Ledford, "Garage biotech: Life hackers."

<sup>93</sup> Carlson, Biology Is Technology, 132.

<sup>&</sup>lt;sup>94</sup> Carlson and Epstein, "Global Distribution of Commercial DNA Foundries"; Di Justo, "A Genome Shop Near You."

production it replaced. In the case of cocaine, restricted access to markets led drug cartels to innovate and build semisubmersible vessels that can carry illicit cargo worth hundreds of times the cost of the vessel itself. In both cases, the basic policy failure lay in the attempt to control tools and skills in the context of a market in which consumers are willing to pay prices that support use of those tools and skills.

Economic drivers may also reduce the effectiveness of regulations or restrictions built on centralized manufacturing and shipping.



Over the last decade, the cost of synthetic genes has rapidly decreased to just above the cost of synthetic oligonucleotides, which are the raw materials for genes.<sup>95</sup> The difference between these two curves is approximately the maximum profit margin per base achievable by a DNA foundry. Thus as the two curves approach each other, the maximum profit margin has been decreasing exponentially. Given the relentless decrease in potential profit, it is unclear that the industry can be sustained in its current form. As a result, any regulatory framework (voluntary or legislative) that assumes a centralized production model—in essence, a choke point for supplying synthetic genes—is at risk of failing along with the industry itself.

#### Recommendations

For flexibility, I have tried to make a variety of suggestions in different areas and with different levels of implementation difficulty. I tie these recommendations to existing U.S. government policy where possible. An overarching recommendation is that biotechnology proliferation is very different from nuclear technology and should not be treated identically. Overly-restrictive regulations could deprive the United States of the expected benefits of biotechnology (new medicines, greener industry), simultaneously allow other nations to surpass us economically, and not produce a real reduction in risk.

One pervasive issue is the quality and resolution of the data available on the bioeconomy. Monitoring the potential for surprise requires measuring factors, such as GMDP, that not all governments track. I note three possible improvements:

1. The governments of the United States, Canada, and Mexico should consider gathering bioeconomic data about domestic labor, companies, and sectors via the North American Industry Classification System (NAICS). The NAICS "is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy." There is at present no NAICS code for

<sup>95</sup> Carlson, "The changing economics of DNA synthesis."

<sup>96</sup> U.S. Census Bureau, "NAICS - North American Industry Classification System."

biotechnology, thus limiting the accuracy of any U.S. government estimation of biotech economic activity even within U.S. borders.

- 2. The U.S. government should consider formally assessing customs tracking category data to understand better which chemicals and what equipment is going where. This data set could be quite valuable in determining which countries are making progress and in what areas.
- 3. The U.S. government should use the upcoming 2011 Review Conference for the Biological and Toxic Weapons Convention (BWC) as an opportunity to expand international discussion of the bioeconomy. For example, reporting state estimates of biotech economic activity might facilitate conversations in the BWC Confidence Building Measures (CBM) negotiations. Specifically, one CBM might be for states to submit estimates of the size of their biotech industries. This estimate could give an early indication of which countries are experiencing growth in the labor pool skilled in manipulating DNA. Implementing this recommendation would further one goal of the National Strategy, namely to "[revitalize] the [BWC]" by "promoting transparency about legitimate activities".

A second set of recommendations concerns economic policy. The U.S. has the world's largest bioeconomy and an early lead in the marketplace. This sort of lead is difficult to dislodge under rational economics where the market tends to reward the incumbent. Many developing nations understand this and, for that very reason, will try to alter the rules of market. In general, the U.S. economy and long-term security situation might benefit from a coordinated industrial policy that encourages domestic innovation and commercialization of biological technologies while facilitating exports.

- 4. The U.S. government should do as much as possible to encourage domestic firms to consider overseas sales. For example, there is a growing market for biotech reagents in Brazil. If this market can be supplied by U.S. firms then (a) the domestic bioeconomy grows, (b) indigenous development of competition and capability is forestalled, and (c) sales data provide a way of monitoring the pace and direction of research. The U.S. Export-Import Bank could serve as a mechanism for facilitating overseas sales. Biotechnology is not listed among the "key initiatives" at the Bank and, with the Bank's assistance, small biotech businesses could more directly benefit from the rapid growth of the bioeconomy.
- 5. Conversely, the U.S. government should do as little as possible to discourage exports. In particular, onerous export restrictions or excessive bureaucracy will increase economic displacement—primarily in the form of trade that bypasses the United States—with a consequent decrease in transparency. Clarifying the list of products subject to export restrictions would facilitate the understanding of vendors, while also clarifying that those products not subject to restrictions are not to be considered threatening by association.
- 6. The U.S. government should seek to make or enforce level-playing field international trade agreements. For example, in 2010 China signed the World Trade Organization's Government Procurement Agreement, which regulates free trade in government contracts. An immediate item for consideration under the treaty should be China's indigenous innovation requirement for government contracts.
- 7. The U.S. government should avoid regulatory actions that restrict domestic access to biological tools and technologies. The National Strategy asserts the importance for U.S. security of the international development and understanding of biological technologies. The National Strategy

also asserts the importance for U.S. security and economic growth of widespread domestic innovation in biological technologies. Realizing long-term security benefits from such innovation requires that individuals and small organizations have continued access to biological technologies. Prior efforts to improve domestic security through restriction of access to production technologies used in the manufacturing and distribution of alcohol and illicit drugs have been counterproductive and reduced security. These outcomes are rooted in the attempt to control tools and skills in the context of a market in which consumers are willing to pay prices that support use of those tools and skills. Above all, the U.S. government should avoid actions that create perverse incentives to develop black markets for biological technologies.

8. The U.S. government should base biosecurity policy upon data. To that end, because the international proliferation of biotech skills and materials is demonstrably driven by economics, the U.S. government should fund an ongoing assessment of the investment in, and the growth of, the international bioeconomy. Objective Three of the National Strategy is to "obtain timely and accurate insight on current and emerging risks" by "ensuring appropriate Federal investments in 'technology watch' initiatives". This report demonstrates that industries, and indeed state economies, can be shifted in emphasis within just a few years, driven by proliferating biotech skills and capabilities. This report also demonstrates that many countries are investing heavily in the hopes of further transforming their economies and labor forces. Yet, based on the open sources utilized in this report, the quality of information on the transformation of bioeconomies around the world clearly must be improved to better serve policy and investment decisions by both government and the private sector. An ongoing assessment of the international bioeconomy could be based in government, the private sector, or in academia, with arguments to be made for which investment would provide the best data.

#### **ACRONYMS**

<u>Acronym</u> <u>Definition</u>

BWC Biological Weapons Convention
CBM Confidence Building Measures

FT Financial Times

GDP Gross Domestic Product
GM Genetically Modified

**GMDP** Genetically Modified Domestic Product

**IMF** International Monetary Fund

INR India Rupee

IT Information Technology

MoE Ministry of Education [China]

NAICS North American Industrial Classification System

NBS National Bureau of Statistics [China]

NS North-South

**NSF** National Science Foundation [United States]

**OECD** Organization for Economic Cooperation and Development

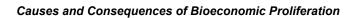
**R&D** Research and Development

SS South-South

**USD** United States Dollar

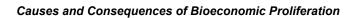
USDA United States Department of Agriculture
USITC United States International Trade Commission

WSJ Wall Street Journal



### **GLOSSARY**

- **biologics**. Medicinal products such as vaccines or recombinant therapeutic proteins created by biological processes (as distinguished from chemistry).
- **black hat**. A computer hacker that is viewed as evil. They may break into computer systems or write malware such as viruses.
- **glocalization**. The adaptation of a global phenomenon to local conditions.
- **R&D Intensity**. For a nation, the amount of R&D investment divided by the GDP. It measures a country's prioritization of science and technology.
- sea turtle. The Chinese term for an individual who has left China to study or work overseas, but has now "swum home". The individual often brings back valuable knowledge about a particular field. (See also "seagull")
- **seagull**. A term that refers to Chinese students who graduate from universities overseas and "migrate" back and forth for work. The individual may be a professor, for example, who teaches half the year abroad and half in China. These individuals often maintain a valuable flow of information to China. (See also "sea turtle")



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### APPENDIX A: DEFINITION OF BIOTECHNOLOGY

Biotechnology does not have a uniform definition around the world. It may exclusively include products generated using genetic modification, or it may more broadly include the products of fermentation or purification processes.

This definitional issue leads to confusion that can extend to false conclusions. Even GM crops, which nearly all concerned would describe as biotechnology, are subject to misclassification. For example, until December of 2009, the worldwide press misreported the revenues from GM seeds as being the total for GM crop revenues." This incorrectly minimized the importance of agricultural biotech by a factor of 30...

To better understand what data is being collected it is helpful to examine the practical definitions being used on daily basis. The Organization for Economic Cooperation and Development (OECD) bases its analyses on survey data from respondent countries, who are provided both with a list-based definition of biotechnology that encompasses a wide variety of processes and subject matter in molecular biology, chemistry, and genetics, and with a single definition of biotechnology, as follows: "The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."

The USITC, in a survey of China, used the following definition for industrial biotechnology: "The manufacture of liquid fuels and chemicals using (1) enzymes or micro-organisms at any stage of the production process, regardless of the type of raw materials used (e.g., renewable, fossil fuel-based, or inorganic); or (2) renewable resources and conventional chemical processing." "

<sup>97</sup> Carlson, "The market value of GM products."

<sup>98</sup> OECD, "A FRAMEWORK FOR BIOTECHNOLOGY STATISTICS."

<sup>99</sup> Nesbitt, "Industrial Biotechnology in China Amidst Changing Market Conditions."



# APPENDIX B: QUALITY AND AVAILABILITY OF OPEN INFORMATION SOURCES

The global proliferation of biotechnology will pose new intelligence gathering challenges for the United States. Greater participation in the manipulation biological systems will require assessing a much larger number of actors. Distributed development and local use of biological technologies will compound the difficulty of gathering necessary data.

The research leading to this paper was designed to be an exercise in collecting and analyzing open source information. It is therefore necessary to address the quality of open source information.

The type of data and analysis available in open information sources varies greatly depending on the subject country. For instance, a Google search using the terms "industrial biotechnology India" returned a mix of documents dominated by reports published by the government of India, advertisements for educational programs, and only a small number of reports published by consulting firms. In contrast, a search on the terms "industrial biotechnology China" returned a mix of market analysis by private firms, reports by U.S. government agencies and international organizations, and a large number of academic papers examining all facets of research, development, commercialization, and international market share.

The General Utility and Reliability of Statistics in China: Here I would note that on the same day in March 2010, based on government statistics, the Financial Times (FT) and the Wall Street Journal (WSJ) came to exactly opposite conclusions about the future of a Chinese real estate bubble. Here is the WSJ headline, "China's Real-Estate Boom Appears to Cool," and here is the FT headline, "Fears grow over China property bubble despite efforts at cooling." One explanation for this confusion can be found in a story from Xinhua a few weeks earlier: "China statistics chief admits errors in property data caculation [sic]" in the confusion can be found in a story from Xinhua a few weeks earlier: "China statistics chief admits errors in property data caculation [sic]" in the confusion can be found in a story from Xinhua a few weeks earlier: "China statistics chief admits errors in property data caculation [sic]" in the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be found in a story from Xinhua and the confusion can be confusion can be confusion can be confused in the conf

Due to staff shortages, housing price data mainly stemmed from reports by real estate developers, said [Ma Jiantang, director of the National Bureau of Statistics (NBS)], who cited Beijing as an example where only one or two officials were responsible for collecting data from hundreds of real estate companies.

"Under the circumstance, we have to rely on the employees of property companies after giving them short-term training," Ma said. "And some of the employees lack professionalism and a sense of responsibility."

There is little reason to think this phenomenon is limited to real estate. Indeed, the ultimate calculation of GDP is somewhat uncertain. See for example, a recent story from Xinhua, "China mulls unified GDP calculation":

China's top economic planning body has confirmed that China is considering bring local GDP under unified calculation in an effort to prevent local officials from cooking economic growth figures for political benefits.

...In the first half of 2009, the sum of provincial GDP figures was 1.4 trillion yuan more than the

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<sup>100</sup> Batson, "China's Real-Estate Boom Appears to Cool"; Anderlini and Mitchell, "Fears grow over China property bubble."

<sup>&</sup>lt;sup>101</sup> Xinhua, "China statistics chief admits errors in property data caculation (sic)."

<sup>&</sup>lt;sup>102</sup> Xinhua, "China mulls unified GDP calculation: NDRC."

national figure, calculated by the NBS independently. Almost half of the provincial governments reported a double-digit GDP growth whereas the national growth figure was only 7.1 percent.

Thus the numbers I report in the biotech area should be subject to some reasonable skepticism. However, while the numbers may be off by a few percentage points, as in the case of GDP calculations, I do not think they are off by as much as 10 percent.

In general, data concerning biotech in China is murky. For example, according to the OECD, survey data from China (Shanghai only) suggest that as of 2006, 53% of biotech companies there employed fewer than 50 people. <sup>103</sup> But OECD reports are based on voluntary surveys, in this case only from Shanghai, and it is unclear that the numbers are a representative sample for Shanghai, let alone the rest of China. In contrast, the OECD has substantially more data provided by hundreds to thousands of respondents each from the United States and European countries.

The numbers on education commonly available for India and China are also deeply suspect. Even in an area like engineering, recognized as critical to economic success and therefore relatively well studied, data are either poor or difficult to compare between countries. For example, one comparative study revealed that the Chinese Ministry of Education (MoE) compiles degree statistics reported by the provinces, but the provinces use different definitions of "engineering". Interviews with MoE officials confirmed that any degree with the word "engineering" in the title is included in the graduation statistics, potentially leading to the inclusion of "motor mechanics and industrial technicians" in the count of "engineers". The accuracy of the count is further degraded by the inclusion of two- and threeyear degrees in the total. In India, the study found that the most prominent source of information on graduates relied on the total maximum allowed enrollment adjusted with historical graduation rates; that is, rather than a measurement it was fundamentally a guess. 105 Follow-on interviews by the authors revealed that registrars at many Indian universities "were unable to tell our researchers how many engineering students they graduated or enrolled, or were uncertain how many colleges were affiliated with their university system." The researchers also found a very clear effect due to the highly variable quality of the engineers in question. Top-level graduates, who are relatively few in number, were in high demand, while mid- and lower-level graduates were often unable to find employment. In summary, the researchers reported that relatively few of the engineering graduates in India and China were as capable as the average U.S.-trained engineer, and that the number of engineers graduated annually by China and India were each inflated by more than a factor of 2.

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<sup>&</sup>lt;sup>103</sup> van Beuzekom and Arundel, "OECD BIOTECHNOLOGY STATISTICS - 2006."

<sup>&</sup>lt;sup>104</sup>Gereffi et al., "Getting the Numbers Right."

<sup>105</sup> Ibid.Ibid.

# APPENDIX C: SUGGESTED METRICS AND COUNTRY INDICATORS

### **Suggested Metrics**

- 1. Genetically Modified Domestic Product (GMDP): Revenues from products produced using genetically modified organisms.
- 2. Skilled labor, or the change in skilled labor approximated by annual graduation rates.
- 3. Surplus labor, or as a proxy, wages for skilled labor that may indicate an oversupply.
- 4. The number of developing countries engaged in South-South R&D or commercial collaborations.

### **Country Indicators**

Country	Indicator
China	GMDP, surplus labor, training of foreign labor, exports
Pakistan	GMDP, education, positive change in access to capital, number of spin-outs from government labs
India	GMDP, employment rate

