Center for Biosecurity of UPMC

The Industrialization of Biology and Its Impact on National Security

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# The Industrialization of Biology and Its Impact on National Security

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The Industrialization of Biology and Its Impact on National Security:
Summary of Findings

The Center for Biosecurity of UPMC (the Center) conducted a horizon-scanning project to provide senior leaders from the United States and the United Kingdom with awareness and understanding of the medium-term future of biotechnology and biological dangers, resulting strategic concerns for homeland and national security, and possible approaches that both countries may take to address biological dangers.

Biology is on the cusp of becoming a pervasive industrial technology.

Economically and strategically important industries are increasingly relying on biological manufacturing processes for fuel, agriculture, medicines, and products that traditionally have been made using chemistry. The industrialization of biology, akin to the introduction of steam engines or computers in ushering in a new technological age, has major national security implications in terms of peer competition, sources for precursor materials, availability of critical pharmaceutical drugs, and the global accessibility of powerful technologies. There are technical barriers, including software development and the difficulty in managing large datasets, that could potentially limit the pace, but not the end result, of biotechnology industrialization.

As a consequence of biological industrialization, the “who, what, and where” of bioscience—what project participants termed the biotech ecosystem—is changing.

Concerns were expressed about the need for established centers of biotechnology, including the U.S. and U.K., to adapt to the global competitive market for bioscience. Peer country competitors, including Brazil, China, Russia, and India, have made substantial economic gains from biotechnology and are competing with other bioscience regions for manufacturing resources, consumer markets, and skilled workers, with implications for national security.

Industrialization will inevitably increase the potential for misuse of biology.

The advent of powerful new technologies expands both the possibilities for nefarious use by malicious actors and the number of potential actors who are technically able to misuse bioscience. Collectively, the global accessibility of powerful biotechnologies, information, and training; the “de-skilling” of molecular techniques; and the beneficent uses of biotechnology indicate that most biological dangers will be impervious to central control or regulation on a global scale. It will also be difficult to maintain appropriate individual vaccines and therapies for an increasing range of biological dangers, whether they stem from misuse, accident, or nature.

Biotechnologies have untapped potential to empower national security.

In this new industrial biotechnology future, national-level strategies are required to stay competitive and to maintain domestic biotechnology capabilities for national security. Advances in the biosciences and biotechnologies should enable the development of diagnostics, the rapid development of medical countermeasures, and the means to evaluate the effectiveness of those countermeasures. It should also provide positive contributions to diagnostics to aid in the rapid detection of natural or deliberate disease and to help guide response. Shepherding these technologies requires good management and funding of science and technology and the right regulatory approach.
The Industrialization of Biology and Its Impact on National Security

Purpose

The Center for Biosecurity of UPMC (the Center) conducted a horizon-scanning project to provide senior leaders from the United States and the United Kingdom with an expert assessment of key bioscience developments in a 5- to 10-year timeframe, the resulting concerns for homeland and national security, and suggestions for what the U.S. and U.K. may do to address them. The Center also examined the drivers of likely advances, barriers to advancement, and ways in which dangers might be mitigated.

Methods and Analysis

Interviews: The Center interviewed 46 leaders (listed in Appendix B) from the biosciences and related fields from academia, government, and the private sector, including venture capitalists. Our goal was to ascertain the experts’ judgments about evolving capabilities in the life sciences and the accessibility of those capabilities.

Our discussions focused on trends in capabilities as opposed to details about specific technologies, because technologies are interdependent, and the experts with whom we spoke often work at the interface of categorically distinct technologies, such as synthetic biology and bioinformatics. Our analysis also captured insights into newly emerging technologies that are not widely visible.

We asked in interviews how bioscience capabilities are likely to evolve over the next 5 to 10 years and about the drivers that could affect the trajectory of that evolution. Such drivers include, but are not limited to, commercial market and medical research interests, regulatory pressure, investments in education, intersections with other technologies, government support of national industries, and the effects of the global economic downturn. We focused on how accessible new capabilities would be to nation states, small groups, or individuals—for entrepreneurship, or recreation (i.e., do-it-yourself biology, aka DIY Bio, or citizen science), or for malevolent purposes. We asked about potential dangers and homeland security concerns that could emanate from these capabilities, and how such dangers or concerns could be mitigated by the U.S., the U.K., or through a collaborative partnership.

U.K. Synthetic Biology Workshop: The Center for Biosecurity participated in the September 29, 2011, Synthetic Biology Workshop organized by Imperial College and the U.K. Home Office, which was a “science-led forward look at the potential negative impacts of synthetic biology.” The participants were a diverse group of U.K. scientists. The deliberations of this meeting informed the subsequent November 9, 2011, Biodangers meeting at the Center for Biosecurity and this project report.
Review of published literature and previous reports: The Center analyzed and included relevant data from available published horizon-scanning assessments of technology, which included the following: (1) U.S. National Research Council report *Globalization, Biosecurity, and the Future of the Life Sciences* (2006), which described such scientific trends as acquiring novel molecular diversity, directed design, and intentional manipulation of biological systems; (2) commercial, medical, and industrial applications; and (3) the 2011 report *Life Sciences and Related Fields: Trends Relevant to the Biological Weapons Convention*, which described the weaponization potential of bioscience capabilities.\(^1\)\(^2\)

November 9, 2011, Biodangers meeting: The Center completed a preliminary analysis report that synthesized the results of both the literature review and our expert interviews. Those findings were used to facilitate the discussion in the November 9, 2011, Biodangers meeting at the Center for Biosecurity in Baltimore, MD, USA. That meeting was attended by participants from U.S. and U.K. academic institutions, private industry, the U.S. government (USG), and the U.K. Home Office, which funded the travel of the U.K. participants. Appendix A lists all meeting participants. Senior staff and leadership from the U.K. Home Office, the Defense Threat Reduction Agency (DTRA), the Department of Homeland Security (DHS), the Center, and The Tauri Group participated.

The meeting served as a forum for in-depth discussion of the direction of biotechnologies, the challenges and priorities for the USG and U.K. Home Office in promoting positive uses of biotechnologies, and potential biosecurity needs that the U.S. and U.K. could pursue in the medium-term, either collaboratively or separately. Diverse views were encouraged in this discussion, and while there was no requirement for consensus, there was substantial agreement around many findings.

Final report: This final report presents the Center’s scientific and policy assessment of this issue, informed by our expert interviews, literature review, and U.S. and U.K. meeting discussions. The views expressed do not necessarily reflect specific views of the meeting participants or sponsors.

Offset quotes: Throughout this report, the offset quotes that appear in the text were from individual meeting participants. They are anonymous as per agreement with the project participants.

Funding: This project was funded by the DTRA Chemical and Biological Technologies Directorate DTRA/RD-CB) through The Tauri Group.
Finding 1. Biology is on the cusp of becoming a pervasive industrial technology.

Biology is on the cusp of becoming fully industrialized. Economically and strategically important industries increasingly rely on biological manufacturing processes for fuel, agriculture, medicines, and products that have traditionally been made using chemistry.

This section of the report describes the growth of biotechnology industries, as well as technical barriers that could potentially limit the pace, but not likely the end result, of biotechnology industrialization.

*In the 1800s, we saw huge changes from the invention of the steam engine and the ability to create and distribute energy. In the 1900s, we saw revolutionary changes from electronics and the ability to manipulate information. The major change in this century will be biological control over manufacturing. From an engineering perspective, biology is about making things—it’s a manufacturing technology. It puts atoms precisely where they should be.*

### Biological Approaches Gaining Industrial Significance

**Industry is increasingly reliant on biological approaches.** Biological processes have long been used for industrial purposes. Agriculture, biologics, pharmaceuticals, and fermented products (such as beer and wine) all require biological processing steps. Yet, the industrial use of biology is extending into areas that have traditionally required either chemical engineering or resource-intensive harvesting from nature. For example, artemisia plants have been used for medicinal purposes since at least 200 BC but on a small scale; now, a synthetic version of artemisinin can be mass produced, so that the World Health Organization (WHO) may use it in sub-Saharan Africa to treat malaria patients.³

Medicines are only part of the industrialization of biology. Analysts have forecasted that by 2015, one-fifth of the U.S. $1.8 trillion chemical industry could be dependent on synthetic biology.⁴ Over the course of the next decade, the synthetic biology market has the potential to grow to US$3.5 billion based on its industrial relevance.⁴ This is due to investment in biofuels and chemical processes, such as bioisoprene to make tires traditionally produced from natural rubber, or valencene, an orange flavoring used in perfumes and food products, or any number of detergents, adhesives, and building materials. Mining is another example: Biological organisms are currently used in gold mining, because it is cost-effective, safer, and less environmentally damaging compared to traditional extracting methods using cyanide.⁵ In the future, synthetic organisms may be designed for extracting rare earth metals, essential for lasers, magnets, and electronics. Rare earth metals are not rare in nature, but the expense of extraction and toxic byproducts, coupled with aggressive market strategies, has resulted in the U.S. purchasing most rare earth materials from China, even though there are plentiful domestic natural resources.⁶

In addition to mining, there is a potentially vast body of information relevant to other industries that may be gained from the harvesting and study of natural organisms. Extremophiles, for instance, are organisms that thrive in habitats unsuitable for most life forms. They can be found in environments
of high heat, dryness, or salinity, or in habitats of low pH or high pH, or in places with high levels of radiation—all habitats that require adaptations that could inform industrial manufacturing processes and environmental remediation. Further, it may not always be necessary to harvest from the natural environment: There is a great amount of genetic flexibility within organisms that could be tapped in a laboratory for industrial applications.

Increased Computing Power Available

Increased computing power is driving new bioscience approaches and applications. In the coming years, biological systems are expected to become more predictable to scientists, and thus more amenable to engineering. Increased computing power available to scientists and engineers, along with inexpensive DNA sequencing and synthesis technologies, will allow many permutations of biological systems to be synthesized and tested. Computational biology is consequently expanding as a field, along with its requirements for applied mathematics, software engineering, data storage, and algorithm development.

According to the scientists interviewed, the effects of increased data-crunching power are only beginning to be realized; they expect that enhanced computing power and accessibility will lead to improvements in drug development and diagnostic tests, as well as improved modeling of biological systems, interpretation of genomic datasets, and manipulation of smart materials.

The bio community doesn’t yet understand how much computer power will be available and what it means.

In addition to computing with petaflops in high-resource settings, computing power is also more accessible to all scientists. A 2011-era smart phone has more processing power than all the computers in the Apollo 11 Lunar Lander, which put 2 people on the moon. Computing power may help to form new industries around next-generation investigative tools, which will include advanced sequencing capabilities, improved management of biomedical databases, and electronic medical and high-volume automated image-screening technologies.

Just as computing power stands to transform our understanding of biological systems, biological systems themselves may provide computational power. Nature has evolved to use genetic material to both store and act on information; this process is now being put to industrial use.

Nanotechnology is about building tiny machines, and biology worked that out a long time ago.

There are already in existence computers that use DNA instead of silicon to perform calculations. These biological computers, sometimes called matter computers, have already performed simple calculations, such as square roots, in a test tube, and they may eventually contribute to the industrial potential of self-healing plastics or point-of-care diagnostics that do not require refrigeration. As recently demonstrated in vitro, an RNA-based circuit was able to distinguish cancer cells from noncancerous cells and trigger the cancer cells to self-destruct.

Data Management Challenges

Managing and interpreting an explosion of data will be a challenge. Technical challenges ahead include that of storing massive amounts of biological information. Right now, more than 2% of the electricity in the U.S. is consumed by datacenters. It is expected that to support the technology of today, the equivalent of about 45 new coal plants will be needed to power U.S. datacenters by 2015 if there are not dramatic improvements in efficiency.

In addition to the costs of storage, there are technical challenges in manipulating such large amounts of information. One of these challenges is software-based. While there have been great strides in advancing the multiprocessing capabilities of computers, software development to take advantage of multicore processing has lagged behind.
The cloud includes almost limitless data storage and processing, but the software infrastructure isn’t there to harness parallel processing capability.

Further, information for bioinformatics analysis has to be in a computable form, but often it is not. Scientists have to be able to generate data in a form that is accessible for others to compute if potential benefits for medical diagnostics, health records, genetic analysis, and environmental monitoring are to be realized.

Engineering-Grade Knowledge Needed

Engineering-grade knowledge of biological systems is needed. To be able to use DNA and other biological molecules for engineering and industrial purposes, their functions must be understood at the smallest scale, which is a new requirement.

There are also many areas of biological science that require resource-intensive efforts, such as gene characterization, which won’t be substantially sped up through reductions in the costs associated with sequencing or by enhanced computing power. True understanding of biological systems may be slowed by the time it takes to understand these biological systems at the detailed level needed for engineering.

What can I do with 10, 20, 50 genes? It comes down to knowing what each part does, and too few scientists are doing the hard work to figure that out.

One scientist noted that when inexpensive DNA sequencing became available to researchers in 1996, a large number of scientists adopted sequencing as “the thing to do.” While sequencing studies are valuable, too few scientists are engaging in the time-intensive work of learning how individual proteins function and how complexes of proteins interact.
Finding 2: Industrialization and peer competition are altering the “biotech ecosystem.”

The “who, what, and where” of bioscience industries—what project participants termed the biotech ecosystem—is changing. Several project participants were concerned that not enough is being done in some established centers of biotechnology to adapt to the changing biotech ecosystem and remain competitive. In contrast to other industries that require substantial natural resources, such as arable land, oil, or natural gas, biotechnology has few barriers to entrance, and emerging markets can become competitive quickly.

This section of the report describes how the biotech ecosystem is changing, and how peer country competitors have made substantial economic gains from biotechnology in a short period of time and are competing with established bioscience regions for manufacturing resources, consumer markets, and skilled workers—actions that all have implications for national security.

The center of gravity is going to change dramatically where biology is practiced, and that will catch people by surprise. We’re going to see a tremendous shift to the developing countries, to the growing economies, and less and less attractiveness of biology in the industrialized world. It’s going to surprise people how quickly that future is going to come.

Biotechnology Has Low Barriers to Entrance

Entry barriers to bioscience and biotechnologies are low. While bioscience research practice has recently trended toward use of large, multidisciplinary teams, the field is still open to individuals or small groups. Due to increasing accessibility of biological techniques (referred to as “de-skilling”), scientific experimentation is increasingly open to and practiced by amateurs. Citizen science, or DIY Bio, has gained popularity in recent years and has led to the creation of community laboratories in Brooklyn, San Francisco, and Manchester, England.

Some analysts have predicted that these laboratories will result in innovative new biotechnologies, but most scientists interviewed for this analysis had more modest expectations. They observed that more DIY Bio enthusiasts are working on such projects as DNA barcoding, a taxonomic method to determine species that is useful for detecting intentionally mislabeled fish, or on mining personal genetic data. Another example of amateur involvement in biotechnology is iGEM, the International Genetically Engineered Machine Competition. This is a competition in which undergraduates from around the world build simple synthetic biological systems from standard, interchangeable parts, called BioBricks, and operate them in living cells. iGEM grew from 5 teams in 2004 to 165 teams in 2011, with 8 to 12 students per team. A Slovenian team won in 2010 for designing a DNA-guided assembly line. The 2011 winner was a team from the University of Washington for its project called Make It or Break It: Diesel Production and Gluten Destruction, the Synthetic Biology Way. Though iGEM projects are carried out by students, many of them entirely new to bioscience, the projects have been sophisticated, and they demonstrate the accessibility of biotechnology techniques to interested, dedicated groups.

The ability of small groups to accomplish meaningful biological projects has implications for the
No matter where I am in the world, I have access to almost the same tools that you have inside the Venter Institute. They might not have the concentration of minds who do lots of different things who are brought together under a common vision. But there are a lot of really smart people out there who will do amazing things or do horrible things.

The 2010 iGEM win of the team from Slovenia, which is not among the top 10 countries in science and engineering, demonstrates that a few people performing at a high level can outdo groups with more resources.\(^{18}\)

Movement Toward Large Interdisciplinary Teams

High-resource laboratories are moving toward large, interdisciplinary teams that span expertise in biological systems and applied mathematics. Work in the biological sciences is increasingly international and interdisciplinary. Major advancements in biotechnology are increasingly being accomplished by teams of biologists, engineers, chemists, statisticians, computer scientists, biophysicists, mathematicians, material scientists, and researchers from other disciplines, working together in large teams. One example of this shift was the Venter synthetic cell project, which took 20 people 10 years to complete, at a cost of US$40 million.\(^{19}\) Another example of big biology is the Human Microbiome Project. Launched in 2008 by the U.S. National Institutes of Health, it is a 5-year, US$157 million effort to understand the complexity and diversity of microbes that live in or on the human body.\(^{20,21}\)

Multidisciplinary biological studies that incorporate mathematicians and engineers may now be considered the substrate for biotechnology industrialization, but this is a radically different organizational approach than has been used in the past, which focused on supporting individual scientific investigators.

Universities and government agencies, at least in the U.S., have real difficulties in nurturing and managing multidisciplinary teams.

Funding sources may not appreciate the value or might not be able to properly evaluate

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FIGURE 1: Number of Biotech Articles Published by Region.

interdisciplinary work. It is also a challenge to educate professionals from the biological sciences and from engineering so they are able to participate and engage in multidisciplinary work and can understand the technical terms, perspectives, and constructs of other fields. New models of operating, educating, funding, and collaborating will have to be developed to maintain competitiveness.

Peer Competition Increasing

Peer competition is changing the biotech ecosystem. Project participants agreed that peer competitor countries are making substantial strategic investments and taking risks to promote innovation in the biosciences, and they are gaining from these strategies.

China’s government is spurring investments in biotechnology, and the sector is seen as a key source of economic development for the future. During its twelfth 5-year plan period, the Chinese government will spend 20 billion yuan (US$3.15 billion) on innovation in medicine, cultivation of genetically modified organisms, and prevention and control of infectious diseases, according to the China National Center for Biotechnology Development. The goal is to have biotechnology account for 15% of the nation’s GDP by 2020. Currently, it accounts for 3% of China’s GDP.

China’s investments to date were not appraised uniformly by those we interviewed: One government expert classified the Chinese biotechnology enterprise as “lavish and fast-moving” and emphasized that the U.S. is lagging behind. Other experts interviewed were more sanguine, predicting that the U.S. will maintain an edge due to its patent and venture capital systems.

One tangible and successful example of China’s commitment to a biotechnology future is the Beijing Genomics Institute (BGI), which boasts 128 Illumina HiSeq 2000 sequences, or 3 times the number that most sequencing centers have. They have more than 4,000 employees, including more than 1,000 bioinformaticians, and they have tremendous government support, as evidenced by a 2009 government loan equal to US$1.5 billion.

BGI was a key player in the analysis of the 2011 E. coli O104:H4 outbreak, and its scientists have analyzed more than 50,000 samples, including tens of thousands of whole human genomes and exomes.

FIGURE 2: U.S. Drug Sales by Volume.
They are currently able to sequence the equivalent of 2,000 full human genomes in a single day.\(^{23}\)

While China’s gains in biotechnology are impressive, venture capitalists and biotechnology industrialists emphasized that China is not the only competitor. *China is the 800 pound gorilla, but even if we focus on the 800 pound gorilla, we can’t lose focus on the 600 pound gorillas, which include Russia, Brazil, and India.*

Russia is planning to have a 5% share in the global biotechnology market by 2020.\(^{24}\) The experts we interviewed found those predictions to be credible, based on Russia’s past technology investments.

A venture capital industry expert contrasted the deliberate, focused strategies of other countries with those of the U.S., noting that his firm funded a biofuels company “that could one day produce oil at $20 a barrel,” but was turned down for investment by the U.S. Department of Energy. They have since moved operations into Russia and the Middle East.

Brazil, Russia, India, and China, in addition to being centers of innovation, have growing markets for biotechnology and pharmaceutical products, which will draw increased attention from private companies. Brazil, Russia, and India are expected to add US$5 billion to US$15 billion to the pharmaceuticals market through 2013, and all 3 countries have had double-digit pharmaceutical growth over the past few years.\(^{25,26}\)

**Shifts in Biotech Ecosystem Connected to Drug Shortages**

**Pharmaceutical drug shortages are a growing problem.** As a consequence of the shifting biotech ecosystem, most pharmaceutical drugs are imported, and thus may not be available in an emergency. U.S. and U.K. dependence on foreign manufacturing capability has already been a factor in drug shortages, especially for cancer therapies. In an October 31, 2011, executive order, President Barack Obama stated that “[s]hortages of pharmaceutical drugs pose a serious and growing threat to public health,” and he gave the U.S. Food and Drug Administration (FDA) broadened powers to require additional reporting to predict shortages and expedited regulatory reviews of substitutes.\(^{27}\)

Critical ingredients for most antibiotics are now

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**FIGURE 3:**

*Venture Capital Investment in Life Sciences.*


*National Venture Capital Association.*

made almost exclusively in China and India, as is prednisone (steroid), metformin (for diabetes 2), and amlodipine (antihypertensive). Indian companies currently hold 22% of the world generic drug market.

*If there is a serious dislocation of international supply chains, conventional pharmaceuticals would not be available. We’d see panic in society. Major hospitals receive 2 to 3 deliveries a day to minimize shelf inventory.*

Meeting participants suggested a potential synthetic biology solution to this problem: First, identify those critical industrial chemicals that if in short supply would create shortages of critical drugs; then, apply biological processes and techniques to synthesize those chemicals; finally, stockpile the organisms that produce those critical chemicals rather than the chemicals themselves.

An attractive aspect of funding such an approach is that the regulatory requirements that have to be met to establish a particular level of purity for an organic product created through a synthetic biology process are not as stringent as those required when replacing entire drugs and drug pathways.

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**Critical to Remain Competitive**

**The U.S. and the U.K. must prepare for a changing ecosystem while remaining competitive.** Among those interviewed, there was a great deal of concern that the U.S. and U.K. are not doing enough to remain competitive in a biological future, and that future industries would be formed by and cater to other markets. This issue is also highlighted in the recent U.K. government life sciences strategy.28

Project participants were concerned that the U.S. and the U.K. did not have the workforce required for a biological future.

*Nearly all applicants to my company arrive from outside the country—mostly from China and Russia. Where is all the training going on? It doesn’t seem to be here in the U.S.*

Many scientists interviewed thought that U.S. and U.K. training is not producing enough people geared toward the engineering, math, and biotechnology professions. There were also concerns that continuing education for professional scientists is not effective, and there is a need for training biologists to take advantage of the large datasets that are available to them.

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*FIGURE 4: Many Chinese Scientists Are Looking to Split Time Between U.S. and China.*


Adapted with permission.
In the Biodangers meeting, some scientists complained that U.S. immigration policy makes it overly difficult for U.S. companies to retain highly skilled foreign talent. Once postdocs are trained, they may have to return to their home countries regardless of their wishes or their levels of training. Current U.S. law allows for the award of approximately 120,000 employment-based visas per fiscal year, of which no more than 7% can be awarded to any single country, regardless of that country’s population. Thus, highly skilled workers from such populous countries as India or China could end up waiting indefinitely for a U.S. visa. In fact, the waiting time for permanent resident visas for educated workers from India is now 70 years.29

Other data, however, indicate that the decline of the U.S. economy and the rise of emerging economies, rather than U.S. immigration policy, are to blame for the loss of foreign talent. A survey of Chinese and Indian immigrants who studied or worked in the U.S. for at least 1 year before returning home found that the majority—86.8% of Chinese and 79% of Indians—were motivated to leave the U.S. by career opportunities in their home countries.30

Regardless of cause, failure to retain highly educated and skilled talent is a boon to other economies. For the U.S., in 2006, foreign nationals were named in 25.6% of all patent applications filed in the U.S., in 65% of Merck’s patent applications, and in 60% of Cisco’s.31

**Hidden Costs of Outsourcing**

**Is biotechnology outsourcing damaging the biotech ecosystem?** While BGI has been a huge success for China, its success in sequencing has raised concerns among the scientists we interviewed about the consequences of outsourced sequencing.

> Some say we should do cheap sequencing in China and do “added value” in the U.K. But if we give up basic skills, we’re giving up the foundation of our work. It is not a concern because it is China, but because they have a monopoly.

Many agreed that wholesale outsourcing could be detrimental to the entire biotechnology ecosystem and could lead to such unintended consequences as the loss of competent workers who gravitate to places where the work is being performed. One meeting attendee described how his company...
outsourced their regulatory studies to save money, but found that by doing so, the company lost substantial training opportunities for their staff. If not planned carefully, outsourcing may lead to the loss of key precursor materials and the knowledge and capability to develop products. For capabilities and products important to national security, this is a concern.

Intellectual Property Barriers

Innovation and industrialization are affected by intellectual property issues. Both the scientists we interviewed and the meeting participants raised concerns about intellectual property and patents. They voiced a worry that current patent structuring does not encourage the collaboration and cross-licensing that has proven successful in the electronics industry. There have also been delays in getting patents: In 2010, the U.S. Patent and Trademark Office reported a backlog of more than 750,000 patent applications, an accumulation that had doubled over the previous decade. Delays in granting patent rights resulting from this backlog could ultimately cost the U.S. economy billions of dollars annually in foregone innovation.

The Biotechnology Industry Organization (BIO), the world’s largest biotechnology organization, maintains that patents often are the “most important and sometimes only asset of a biotech company.” Complicating the issue, however, is an ongoing debate over the patentability of genes and DNA, a capability said by biotechnology experts to be “essential for encouraging innovation,” but condemned by others as not only costly, but unethical.

Multiple project participants expressed strong concerns that the U.S. patent system is not adequately fostering U.S. biotechnology innovation and that China is now poised to surpass the U.S. and lead the world in patent application filings.

The U.S. will lead the way on biotechnology innovation; there is a strong venture capital system and a robust, entrepreneur-friendly patent system. They just need to make sure they don’t lose ground.

Recently enacted patent reform legislation in the U.S. may mitigate these trends. The Leahy-Smith America Invents Act, which was signed into law in September 2011, provides perhaps the most significant changes
to the U.S. patent system since the 19th century.\textsuperscript{40} The legislation introduces a first-inventor-to-file priority rule, prevents patents from claiming or encompassing human organisms, and reforms administrative patent challenge proceedings at the U.S. Patent and Trademark Office. BIO applauded the passage of the patent reform legislation, as did many leading manufacturers, scientists, researchers, academic institutions, and businesses small and large.\textsuperscript{41} Only time will tell whether these reforms are sufficient to enable biotechnology innovators to compete globally.

FIGURE 7: Shares of World Researchers and Per Million Inhabitants (2007).
Finding 3: Biological dangers are persistent.

Biological industrialization is not going to diminish the potential for misuse of biology. Rather, the reverse is true. The advent of powerful new technologies expands both the possibilities that could be explored for nefarious use by malicious actors and the number of potential actors who are technically able to misuse bioscience.

The angles of the attack are almost infinite and very difficult to anticipate.

Collectively, the global accessibility of powerful biotechnologies, information, and training, along with the “de-skilling” of molecular techniques and the almost entirely beneficent use of biotechnology, suggest that most biological dangers will be impervious to central control or regulation on a global scale. It will also be difficult to maintain appropriate individual vaccines and therapies for an increasing diversity of biological dangers, whether they stem from misuse, accident, or nature.

This section of the report describes how project participants assessed the technical requirements of doing harm with new biological techniques.

What we are dealing with is the globalization and commoditization of knowledge. Even if you start with the most sophisticated, cutting-edge research that requires major investments and state actors, this migrates eventually into the community. Almost anybody nowadays can pick up textbooks on methods or read current papers on methods and techniques that 10 years ago were the stuff of Nobel prizes. The knowledge is becoming commoditized.

Options For Harm

Well-resourced groups have many technical options for harm. Without the addition of any new biotechnologies, well-resourced people with scientific training could do a great deal of damage, according to those we interviewed. In the scientific literature spanning the past decade or more, there are many examples of legitimate scientific work that could be misused in order to make pathogens more effective as biological weapons. Indeed, it is well known that the published literature of the past 10 to 15 years includes descriptions of making antibiotic resistant bacteria;\textsuperscript{42,43} of engineering viruses that can escape vaccines, as occurred in the well-known mousepox/IL-4 experiments of 2001;\textsuperscript{44} and for manipulating the genetics of the causative agent of anthrax disease, \textit{Bacillus anthracis}, in a way that allows the organism to escape its vaccine.\textsuperscript{45}

Extinct pathogens, such as 1918 pandemic influenza virus, have already been resurrected.\textsuperscript{46} It also is thought that variola major, the causative agent of smallpox, which has been eradicated from nature, could similarly be synthetically created, though it would be a complicated endeavor.\textsuperscript{47} Smallpox and influenza, of course, have caused infections in living memory. In contrast, the scientists working in the emerging field of paleovirology have been able to resurrect extinct retroviruses that are millions of years old and then demonstrate their ability to infect human cells in vitro.\textsuperscript{48} The consequences of human infection with a previously extinct virus are not known.

The experts interviewed for this project had more specific concerns about how biotechnology could
be misused by skilled scientists and engineers if funding was plentiful and there was tolerance for experimentation. They were especially concerned about food crops, bioengineering novel systemic disruptions, the expansion of the host range of animal viruses, and the use of organisms to attack physical infrastructure, including silicon or rubber.

Another concern raised was a cyber-attack with biological consequences, as would occur if biological data used for industrial, pharmaceutical, or surveillance purposes was tampered with in such a way as to derail decisions and compromise production through application of incorrect data.

Threats from Skilled Individuals

The threats posed by individuals depend on their skill level. Though there are many technically possible misuses of biology, most of the scientists we interviewed thought it unlikely that either individuals or small groups would adopt such approaches. “Old bugs,” such as anthrax, tularemia, and foot-and-mouth disease (FMD), were the biggest worries among those interviewed. In general, they think there are enough relatively simple paths to making a biological weapon to render more technically difficult approaches unattractive and, therefore, less likely to be pursued.

_The bad guys aren’t going to waste their time with sophisticated pie-in-the sky stuff._

The rise of DIY Bio has caused concerns in the media and among policymakers about bioweapons.49,50 Yet, most of the scientists we interviewed are not worried about DIY Bio’s potential for harm.

_People like to equate them to hackers. But you take a hacker and hook them up to the Internet, they have the power of the Internet. DIY people do not have the power of biology._

However, there was a great deal more concern about an expert with the intent to harm—that is, a “bio” Unabomber.

While one person might not be able to accomplish the same biotechnological feats as an experienced team in the same amount of time, new techniques and falling prices for services provide skilled individuals with shortcuts. This potential threat should not be discounted.

Agriculture Is Vulnerable

Agriculture is vulnerable to engineered or natural threats. Agriculture is vulnerable to nonengineered pathogens, engineered pathogens, and introduction of alien species. In our interviews, a great deal of concern was expressed about biological warfare affecting crops or livestock.

There are many known agricultural threats. The U.S. Department of Agriculture (USDA) oversees more than 33 of the 80+ select agents and toxins, including the now-eradicated rinderpest virus, bovine spongiform encephalopathy (BSE, or mad cow disease), and peste des petits ruminants virus. In addition to those known threats, new strains and variants occur regularly in nature. Without adequate fielding of diagnostics, they are often not detected until entire herds or fields are infected.

The archetypal concern for agricultural threats is FMD. FMD is endemic in many parts of the world and is a relatively hardy organism that can survive transport.

_Foot-and-mouth disease is the one I worry about in terms of bringing a country to its knees._

The economic damage of an FMD attack could be considerable: The 2001 U.K. outbreak that was caused by a natural, nonengineered FMD virus resulted in US$10 billion in losses and the slaughter of more than 4 million animals. The costs of a similar outbreak in the U.S. could run as high as US$24 billion plus the lives of approximately 13 million slaughtered animals. An outbreak could be extremely difficult to stop: The USDA calculated that an FMD outbreak could spread to 25 states in just 5 days.51
In addition to engineered pathogens, alien species could be introduced to a new environment, causing tremendous food and economic loss.

A recent example of a natural occurrence illustrates this phenomenon: *Megacopta cribaria*, or stink bugs, were accidentally introduced into the U.S. about 15 years ago and are now present throughout the U.S. and are killing off soybean plants. Naturally spreading plant pathogens could also be introduced expeditiously through a deliberate act, though one current worry—wheat stem rust Ug99, now spreading in Africa, Asia, and the Middle East—is likely to arrive in Europe and the U.S. relatively soon without assistance. A combination of chemicals can currently kill the fungus, and there is intense work going into making genetically resistant seeds, but the clock is ticking.

The effects of agricultural disease, through natural occurrence or intentional introduction, are not bound by borders, as illustrated by the case of naturally occurring South American Leaf Blight (*Microcyclus*), which is the reason rubber is not produced in the western hemisphere, where the rubber tree was originally cultivated. This fungus is currently a threat to Malaysia and Thailand, where rubber production is a major part of their economies.

**Consequential Accidents**

**Biological accidents could be consequential.** Powerful biotechnologies could also result in powerful accidents. Perhaps the most consequential known biological accident occurred in 1977. The seasonal outbreak of influenza that year was caused by an H1N1 strain that was identical to a 1950 influenza strain that had clearly escaped from the laboratory. Other consequential accidents occurred with SARS virus in Taiwan, China, and Singapore in 2003-04, but while the escaped virus caused harm, it did not spread around the globe.

Fortunately, biosafety training and awareness have increased dramatically since 1977, and modern biosafety laboratories have greatly enhanced engineering for biological containment. However, vigilance and training to prevent accidents are still required, especially as biosafety standards are still not uniform worldwide.

Some meeting attendees were concerned that the risk of a laboratory accident increases with interdisciplinary work, which also speaks to the need for additional biosafety training. People entering the field of biology from other disciplines may not have had the training or experience to be safe and take adequate biosafety precautions.

In summary, while biotechnology has the potential to offer exciting new industries, therapies, and products, if misused, the advances merely expand the range of threats. Biological dangers will persist.
Finding 4: Biotechnology has untapped potential to empower national security.

Through peer competition and increasingly accessible and powerful technologies, biological industrialization may have negative effects on national security. However, if advances in biotechnology are accompanied by a national strategy that ensures competitiveness and maintains domestic capabilities, then national security stands to benefit from the growing industrialization of bioscience.

In this section, we describe how advances in bioscience could improve national security by, for instance, enabling the rapid development of diagnostics and medical countermeasures that will be more effective in countering biothreats than what we have now. Also necessary to our ability to reap the benefits of bioscience industrialization will be effective approaches to public engagement, increased and improved scientific education, and regulatory approaches that encourage innovation.

If you had a dangerous technology and were afraid of what could happen as it gets widely known about and released, there are 2 approaches you could take. One would be to try to lock it up and make sure that nobody found out about it. And the other approach is to run like hell [to stay ahead]. And I think the approach here has to be that we run like hell. There’s no way that we’re going to keep the things that we’re talking about secret. We just have to be better at it than anybody else. And we’d just better get on with it.

Reduced Time To Protection

The time to develop drugs, vaccines, and therapies will be reduced. New bioscience knowledge and greater computing power is expected to reduce the time required for all stages of medical countermeasure development, which will concomitantly reduce the risk and financial burden of producing vaccines and drugs. From the beginning of the drug development process, drug target selection will be aided by systems biology approaches. Animal models, which now have great limitations in reproducing the human condition, will be more predictive due to improved humanization of receptors and biological processes. Increasingly, human stem cells will also be used as an in vitro model, offering a better predictor of toxicity.

For manufacturing, an advance already taking hold is the cell-free manufacturing of biologics. This approach should make the regulatory process less burdensome, as batch testing of individual product lots may no longer be necessary and the process may be more akin to the process for chemicals.

Also, clinical trials may be enrolled increasingly through online communities, which should speed enrollment and produce greater statistical power to obtain results quickly. An example of such an online community is the for-profit company PatientsLikeMe (www.patientslikeme.com), which has 118,003 participants with more than 500 disease conditions. The company sells voluntarily collected patient information to many of the Top 20 pharmaceutical companies and engages its members in industry- and government-sponsored clinical trials.

More Powerful and Accessible Diagnostics

Diagnostic tests will become more powerful and accessible. Scientists involved in this project believe that advances in diagnostic tests will supply both healthcare providers and patients with
more information and may produce unexpected diagnoses. Such advances will also enable rapid detection in the event of a disease outbreak and will, therefore, facilitate rapid response.

For diagnostics in the future, it’s not going to be a guessing game. It’ll be [a matter of], “Tell me what’s there, and I’ll figure out if it’s significant.”

Certainly, there will be more diagnostic platforms available, including mass spectrometry, microfluidics, paper-based or cell phone–integrated tests, and multi-analyte and host-side tests. For high-resource settings, the low costs of sequencing could result in routine whole-pathogen sequencing for diagnosis. Human SNP (single nucleotide polymorphisms) analysis and perhaps even whole-genome sequencing of patients may be performed more commonly to aid in diagnosis and preventive care.69

Costs for the human genome have decreased 10-fold over the past 10 years and are expected to decrease another 10-fold in the next 10 years. The recent announcement of a combined Venter/X Prize of US$10 million for more accurate medical-grade whole-human genome sequencing could shorten this timeline.70 There is already notable consumer interest in this type of data: Testament to that is the success of 23andMe, a company that, for $99, will mail out a saliva collection kit to people who wish to have their SNPs analyzed in a CLIA-certified laboratory in order to learn about their personal disease risks. Since it was formed in 2007, the company has analyzed the DNA of 100,000 customers.71

Focus on the Patient, Regardless of Pathogen

Focus on the host, not the pathogen. Efforts are under way to better understand the host reaction to disease, with the goal of modulating individual immunological responses to disease. If that can be done, then genetic modulation of individuals’ immune systems may increase resistance to disease or reduce morbidity. This line of investigation has the potential to shift the focus of medical response away from the approach of fighting a pathogen with drugs tailored specifically to that purpose to an approach based on host immune response more generically. It will allow the medical treatment of the “unknown, unknown,” which is critical to national security in the face of myriad possible variations of the biological threat.

Drug Targets Currently Underutilized

Important drug targets may already be discovered and waiting for development. Finding new drug candidates may not require additional discovery. Discussion in the Biodangers meeting suggested that some biotech and pharmaceutical companies now have in their possession libraries of millions of compounds, many of which have not been tested against pharmaceutical targets or not developed. Governmental pressure to open up pharmaceutical collections for neglected diseases could yield promising candidates.

Drug Shortages Less Likely

Manufacturing can be distributed, which will make shortages less likely. The industrial base is moving toward a dose-on-demand approach to manufacture of pharmaceutical drugs, which could mean that manufacturing will be more geographically distributed and will allow for production of smaller, targeted doses. The vision is to develop an agile capacity to manufacture a variety of batches of drugs that could respond to specific market needs. As a result of this trend, current national strategies for stockpiling medical countermeasures may become outmoded with advances in technologies.

We should be investing in an ability to manufacture countermeasures. And the good news is that biology is going to be the enabling technology that’s going to let us do that.
Medical Practice Slow To Change

Medical practice may not change as quickly as progress is made in the biological sciences. Technological change is likely to be much easier than adoption. Extensive documentation of the slow pace of change in medical practice indicates, for instance, that even when information about new developments is readily available, translation to practice can take as long as 17 years.

As an example: Spine surgery for pain relief has demonstrated no added benefit over other, less invasive interventions, yet 600,000 of those surgeries are still performed each year. For patients with cardiac stents, the news is bleaker: 3 years after the end of the COURAGE study, a well-publicized clinical trial studying heart patients, the important changes to recommended medical practice derived from the study's results have resulted in only negligible changes to the care delivered to patients.

Regulatory Approach Needs To Be Right, or it Could Block Progress

The wrong regulatory approach could limit advances in bioscience. Project participants expressed a great deal of concern about application of inappropriate regulation that could limit the potential for bioscience advances, and they noted that the right regulatory approach that promotes innovation will be essential if bioscience benefits are to be realized.

There is a tendency for regulators to focus on stopping the risk rather than coping with the risk.

Many of the scientists we interviewed believe that current regulations are short-sighted or ill-informed. The example cited most often was the prohibition against genetically modified organisms (GMOs) in the EU, a regulatory decision that has direct costs: If GMOs were allowed, it has been estimated that the profit margins of European farmers would increase by US$443 million to US$929 million each year.

Regulation Being Outpaced by Technological Change

Technology is outpacing the ability to regulate. The resources currently required for evaluating and regulating biotechnologies and products are not sufficient, which does not bode well for the future, as more technologies emerge. In the U.S., FDA-regulated products account for approximately 25 cents of every dollar spent by American consumers each year, but the FDA mandate is considerably more expansive than its budget.

Confounding the problem, new technologies and products may be dramatically different from old models, a problem already apparent with diagnostic tests. Instead of one diagnostic test for one disease, diagnostic tests that detect thousands of pathogens are now possible, but testing and validating them is a new challenge.

Protection of individually identifiable information will also present challenges. Genetic information will become more important to diagnosis and drug development, but as identification gets easier, genetic privacy will be more difficult to control or protect.

Public Engagement—A Must for Technologies to Flourish

Engaging the public is a must. Without public support, emerging biotechnologies may not be allowed to develop or could be banned entirely, as evidenced by prohibitions against GMOs in the EU and bans on stem cell research in the U.S. Clearly, public action can be a powerful impediment to technological advancement. Many project participants were concerned that not enough was being done to engage the public about the future direction of bioscience research and industrialization and the potential benefits to society.

As scientists, we need to get smarter about dealing with the public.
For national security, it is important to make the case for continued scientific research into new ways to diagnose infectious diseases and to prevent or treat using new medical countermeasures. These benefits will not be realized without ongoing commitment to bioscience advances.
Summary

Big teams do not have exclusive rights on the future of biotechnology. Individuals and smaller groups can do the same thing as big life sciences teams on a small scale.

This report is an expert assessment of where bioscience, biotechnology, and the industrial use of biotechnologies are heading in 5-10 years and the resulting concerns and opportunities for national security. The “Age of Biology”—a moniker perhaps first applied at the start of the Human Genome Project in 1990—now is a reality with substantial governmental and private industry support. Industries that traditionally relied on chemical engineering are increasingly reliant on biological approaches, and new industries are being formed as the availability of computational power intersects with the biosciences.

According to the experts we talked to, biological approaches are transforming manufacturing and other industries akin to the way that steam engines or computers transformed nationally important industries. As history has shown in previous industrial revolutions, the center of economic gravity can shift precipitously along with these technological changes, and this is also occurring with biology industrialization. The global biotech ecosystem of available scientific talent, investment, and education is shifting. Peer competitors have been able to leapfrog into established markets with safer and cheaper biotechnologies. Established centers of biotechnology, including the U.S. and the U.K., must adapt in order to remain part of this new industrial revolution, not only with scientific contributions, but by realistically assessing the risks and rewards of the technologies to the public, and with regulatory changes that encourage innovation and private sector investment.

The global industrialization of biology holds additional dangers: the accessibility of new, powerful biotechnologies and information will inevitably increase the potential for misuse of biology. While experts had few concerns about people unskilled in the biosciences using this technology for harm, they were concerned about malevolent use by skilled individuals, especially if they had significant resources. To counter this danger, the only option they foresaw was to tap the potential of biology industrialization to increase protections against misuse. Abstaining from biotechnology development increases national security vulnerabilities, such as diminished medical countermeasures and the loss of economically important industries, but investments in biotechnology, such as in development of medical countermeasures, diagnostic tests, and medical treatments, are not only economically beneficial but also yield national security dividends.
References


Appendix A

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