Backgrounder

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National Security and Biotechnology: Small Science with a Big Potential

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Biotechnology is one of the world's fastest growing commercial sectors. Since 1992, the number of biotechnology companies in the United States alone has tripled. These firms are research-intensive, every day bringing into the marketplace new methods and products that may reshape medical practices and human performance, allowing for unprecedented improvements in health care.

Many of biotechnology's benefits are dual-use, increasing the possibility that knowledge, skills, and equipment could be adapted for use as biological weapons. As the global biotechnology industry expands, the U.S. government should therefore increase its capacity to exploit biotech advances for national security.

The challenge of exploiting cutting-edge biotechnology will be different from the way the Pentagon harnessed science and technology for national security during the Cold War. Rather than driving the biotechnology revolution, the federal government will need to figure out how best to utilize and adapt the products developed by a multibillion-dollar transnational industry that already has the money and capacity for research and development.

To keep up, the federal government must adopt legislative, policy, and organizational innovations. These should include promoting international liability protection for developing and deploying new national security goods and services, promoting scientific travel and exchanges, and assigning a lead agency to coordinate biotechnology exploitation for national security.

Talking Points

- Exploiting cutting-edge biotechnology for national security will be different from the way the Pentagon harnessed science and technology during the Cold War. Rather than driving the biotechnology revolution, the federal government needs to figure out how best to utilize and adapt the products developed by the multibillion-dollar transnational biotech industry.
- Much current biotech research focuses on agent detection, vaccines, and treatment. Research is also underway to counter the rise of multidrug-resistant bacteria and develop vaccines and treatments that could provide permanent immunity to all of the "classic" biological agents.
- Congress and the Administration should not only be aware of the growing biotechnology field, but also act to ensure that the private sector remains competitive by streamlining the federal government's capability to fund and adapt new technologies, working to expand litigation protection beyond the country's borders, and further reforming U.S. visa issuance and monitoring programs.

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From There to Here

Biotechnology refers to any technological application that uses living organisms to make or modify products for explicit use, specifically through DNA recombination and tissue culture. Gregor Mendel first described the role of genes through his research on "dominant and recessive factors" in the 1860s. By the 1940s, scientists were aware of DNA, and James Watson, Francis Crick, and Rosalind Franklin modeled its structure in the 1950s.

In 1970, the discovery of enzymes, which break apart and connect snippets of DNA, allowed for the creation of genetically modified organisms. This bore fruit by the early 1980s, when scientists managed to genetically modify bacteria to produce human insulin, which is now the principal source of insulin for diabetics.[1]

Recently, major advances in information technologies have led to the development of bioinformatics.[2] Bioinformatics focused initially on creating and storing biological and genetic information, most notably in the Human Genome Project. Scientists are now combining this information into a comprehensive picture, enabling researchers to study how different diseases alter these activities. Combining advances in genomics and information technology has significantly enhanced the industry's capability to bring new products to the marketplace.

Many of the advancements in biotechnology are dual-use. The technology that may revolutionize medical care by providing faster-acting and more effective drugs could also be used to field more lethal biological weapons. Thus, federal agencies have a clear imperative not only to exploit the advantages of new developments, but also to anticipate and prepare countermeasures for how potential adversaries might exploit these medical advances.

Current Research

Much of the current biotech research focuses on agent detection, vaccines, and treatment. Scientists are studying the immune systems of primitive organisms, such as jawless fish, to garner greater understanding of the human immune system and to develop new antibody therapies.[3] They are also studying how diseases infect and affect human cells. For example, recent research indicates that the family of bacteria that includes bubonic plague blocks immune system responses using a protein related to one naturally found in humans.[4] Scientists are also investigating ways to create vaccines that work against whole classes of disease-causing organisms and to boost the human immune system in general.[5]

Research is also underway to counter the rise of multidrug-resistant bacteria. Scientists are investi-

1. Isaac Asimov, *Asimov's New Guide to Science* (New York: Basic Books, 1984), pp. 627 and 635.
2. Bioinformatics is the use of databases and analytical tools for genome analysis and innovations in molecular biology. One study holds that bioinformatics can reduce the cost of drug development by 18 percent and cut one year from developmental timelines. "The Race to Computerize Biology," *The Economist*, December 12, 2002. Among its many applications to biowarfare, bioinformatics can facilitate the identification of pathogens. For example, see D. A. Henderson, Director, Office of Public Health Preparedness, U.S. Department of Health and Human Services, statement before the Committee on Science, U.S. House of Representatives, December 5, 2001, at *www.hhs.gov/asl/testify/t011205.html* (July 16, 2007). Bioinformatics also holds great promise in developing therapeutic responses to a bioattack. For example, studies show that variations in individual responses to therapeutic drugs are affected by genetic polymorphisms (variations in enzymes caused by slightly different amino acid sequences). Pharmacogenetics employs bioinformatics to assist in decoding and mapping millions of polymorphisms across the human genome, which can provide insights into the links between disease-causing genes and drug-response genes, facilitating the development of new therapeutic strategies. Michael M. Shi, "Diagnostics Meets Therapeutics: The Impact of Pharmacogenetics," *Drug Discovery Today*, Vol. 7, Issue 23 (December 2002), pp. 1161–1162.
3. "Tiny Tampa Bay Fish Key to Evolution of Immune System," American Association for the Advancement of Science *EurekAlert!*, October 2, 2006, at *www.eurekalert.org/pub_releases/2006-10/uof-ttb100306.php* (November 21, 2006).
4. "Study Illuminates How the Plague Bacteria Causes Disease," American Association for the Advancement of Science *EurekAlert!*, September 7, 2006, at *www.eurekalert.org/pub_releases/2006-09/cp-sih090106.php* (November 21, 2006).
5. "Medical College of Wisconsin Researchers Develop Broad-Spectrum Defense Against Germ Warfare: Biodefense Leaps Ahead of One Vaccine for One Germ Approach," American Association for the Advancement of Science *EurekAlert!*, December 9, 2005, at *www.eurekalert.org/pub_releases/2005-12/mcow-mco120805.php* (November 21, 2006).

gating the use of bacteriophages, which are viruses that prey on bacteria, as a means to fight infectious disease. Ironically, research on bacteriophages began in the early 20th century but declined after the discovery of antibiotics. In the summer of 2006, the U.S. Food and Drug Administration approved the use of a bacteriophage preparation on meat as an anti-microbial agent against Lysteria bacteria.[6]

Better vaccines and treatments could provide permanent immunity to all "classic" biological agents or at least reduce their lethality to a considerable degree. In October 2006, the Institute for Soldier Nanotechnologies at the Massachusetts Institute of Technology announced the development of microscopic pumps that would allow rapid testing of blood and other fluids by pumping them into a "lab on a chip," which would detect biological or chemical agents.[7]

Argonne National Laboratory is also developing its own biochip detection technology.[8] This "lab on a chip" research points to the feasibility of rapid biological agent detection, allowing individuals to know whether they have been exposed within minutes rather than days. It may even be possible to develop implantable biosensor chips that would continuously monitor for exposure to biological agents.[9]

The Future of Biotechnology

Future advances in biotechnology will continue to improve the protection of both the general public and military personnel from deadly biological agents. The creation of broad-spectrum vaccines may give the public health community the ability to vaccinate the country's entire population against both endemic diseases and biological weapons. A bioweapon inoculation may someday be as common as other childhood vaccinations.

Besides disease detection and vaccines, biotechnology has numerous other potential applications. The military is exploring the use of biomimicry, which uses natural biological systems or material as an inspiration for solving engineering problems. For example:

- In 2002, scientists discovered how geckos stick themselves to smooth surfaces using van der Waal's forces—the weak natural attraction between atoms—and were then able to re-create the surface of a gecko's foot artificially.[10]
- The Defense Advanced Research Projects Agency is researching devices that mimic geckos' use of van der Waals force to enable soldiers to climb buildings without ropes or ladders.[11]
- Scientists are also researching spider silk and abalone shell to create stronger, lighter armor for personnel and vehicles.
- Other projects include developing organic solar cells and a new generation of sensors and optics derived from biological and silicon-based systems.[12]

The next great step in biotechnology is proteomics: the direct manipulation and construction of proteins. While DNA instructs cellular mechanisms in how to operate, proteins do the actual work inside and outside of cells. Proteins are found in everything from papayas to snake venom. Because protein structure and composition is much more complex than DNA, protein analysis is much more

6. *Federal Register*, Vol. 71, No. 160 (August 18, 2006), at *www.cfsan.fda.gov/~lrd/fr060818.html* (November 30, 2006).
7. Anne Trafton, "MIT Designs Portable 'Lab on a Chip,'" American Association for the Advancement of Science *EurekAlert!*, October 17, 2006, at *www.eurekalert.org/pub_releases/2006-10/miot-mdp101706.php* (October 18, 2006).
8. Donna Jones Pelkie, "Biochip Technology Would Become Standard Diagnostic Tool for Human, Veterinary Medicine," Argonne National Laboratory, November 17, 2006, at *www.anl.gov/Media_Center/News/2006/ES061117.html* (November 21, 2006).
9. Trafton, "MIT Designs Portable 'Lab on a Chip.'"
10. Keller Autumn, "Evidence for van der Waals Adhesion in Gecko Setae," *Proceedings of the National Academy of Sciences*, Vol. 99, No. 19 (September 17, 2002), at *www.pnas.org/cgi/reprint/99/19/12252.pdf* (July 16, 2007).
11. Defense Advanced Research Projects Agency, "Z-Man," at *www.darpa.mil/dso/thrust/matdev/zman.htm* (November 29, 2006; unavailable July 16, 2007).
12. Defense Advanced Research Projects Agency, "Biological Sensory Structure Emulation," at *www.darpa.mil/dso/thrust/biosci/bsse.htm* (November 15, 2006; unavailable July 16, 2007), and "Engineered Bio-Molecular Nano-Devices/Systems," at *www.darpa.mil/dso/thrust/biosci/moldice.htm* (November 15, 2006; unavailable July 16, 2007).

difficult and time-consuming. However, understanding how proteins are constructed and how they behave promises to be as great an advance in biological science as understanding DNA was in the 20th century.

If advances in biotechnology continue, constructing a completely artificial organism from the "ground up"—creating synthetic DNA and proteins from raw materials and then combining them to form living cells—may be possible in the not too distant future.

National Security and Biotechnology

The challenge for the federal government is to figure out how to leverage cutting-edge biotechnology for national security purposes. Before 2001, the Department of Defense (DOD) was the primary arm of the federal government in funding biological defense and research related to national security. The DOD research program focused primarily on the battlefield uses of biotechnology.

The events of 9/11 and the post-9/11 anthrax letters shifted the focus to the American people's vulnerability to biological threats. In many respects, the DOD research was not directly applicable to other biodefense national security needs. For example, DOD immunization programs assume that the individuals to be immunized will be generally healthy and young. On the other hand, immunizations for a general population in the event of biological weapons attack would have to consider the effects of vaccines on old and young people and on individuals with medical conditions who might have weakened or compromised immune systems and react very differently to a vaccine developed by the military.

To apply research to broader national security concerns, the National Institutes of Health (NIH) under the Department of Health and Human Services (HHS) received the bulk of increased funding for developing biodefense measures.[13] In recent years, in addition to HHS and DOD, many other federal agencies have initiated biotechnology research related to national security, including the recently established Department of Homeland Security (DHS). While much of the research in DOD, HHS, and other federal entities involves detecting, protecting against, and mitigating biological attacks and pandemics, it also involves other products related to national security, including human performance enhancement (such as reducing the effects of stress and fatigue) and battlefield medical treatment. There is a plethora of ongoing programs.

The Pentagon has considerable experience and capacity for medical research and development of products related to national security, but this is virtually a new mission for the NIH, which historically has focused on basic scientific research.[14] The U.S. Army Medical Research Institute for Infectious Diseases has unique research facilities and expertise in biowarfare defense. On the other hand, the DOD's record with respect to developing and producing vaccines has engendered significant controversy.

The post-9/11 expansion of the government application of biotechnology to national security has not been matched by organizational innovations to manage and integrate programs more effectively. DOD, DHS, and NIH research programs are not routinely coordinated, and NIH policies prohibit funding other federal institutions. Thus, NIH programs cannot utilize DOD scientists who may have valuable knowledge and experience relevant to NIH national security research. In some cases, government-sponsored research duplicates other programs, and opportunities for complementary research programs are missed.[15]

Enlisting the Private Sector

Harnessing the vast capabilities of the private sector has proven similarly challenging. Compared to potential commercial buyers, the government is a modest-sized customer for biotech firms. There are also other issues. After 9/11, insurance skyrocketed for technologies developed for homeland security.

13. Coleen K. Martinez, "Biodefense Research Supporting the DoD: A New Strategic Vision," Strategic Studies Institute, p. 24, at *www.strategicstudiesinstitute.army.mil/pdffiles/PUB767.pdf* (July 16, 2007).
14. *Ibid.*, pp. 25–26.
15. *Ibid.*, pp. 28–29.

While the demand for new security technologies has swelled, companies must weigh the pressure to rush new products to the marketplace against their liability risks.

In 2002, Congress enacted the Support Anti-Terrorism by Fostering Effective Technologies (SAFETY) Act[16] to encourage companies to continue researching and developing biotechnologies vital to homeland security. The act protects companies from litigation if their products fail during a terrorist attack or are harmfully employed by terrorists. The DHS has shown some success in implementing the legislation and granting SAFETY Act protections to goods and services that are employed to prevent or respond to terrorist threats. However, companies do not enjoy similar protections from other countries when the technologies are deployed outside the United States or adopted by U.S. friends and allies.

The government also has a mixed record in encouraging the private sector to develop new national security capabilities. In 2004, the President announced the implementation of Project Bioshield to accelerate research on and development, purchase, and availability of effective medical countermeasures against biological, chemical, radiological, and nuclear agents. The program provided $6 billion over the next 10 years to private companies for research and development of next-generation countermeasures against anthrax, smallpox, and other infectious agents and antidotes against chemical and radiological threats. To date, the effort has yielded meager results.[17]

The response to 9/11 has introduced another difficulty in advancing biotechnology research in the United States. After the terrorist attacks on New York and Washington, the United States imposed a number of additional requirements on visa issuance and monitoring to thwart travel by terrorists. These measures included more rigorous registration and monitoring of foreign graduate students, mandatory interviews of all overseas visa applicants, and requiring visa holders to return to their countries of origin to renew their visas.

These measures have had unintended consequences, including deterring top graduate students from coming to the United States, making scientific exchanges more difficult, and even prompting companies and academic and scientific associations to move meetings, conferences, and research facilities outside of the United States. As a result, the United States has become less competitive in many key scientific areas, including biotechnology.[18]

Moving Forward

The United States has no room for complacency. Without better policies, programs, and management, it risks losing its competitive advantage in exploiting biotechnology for national security. Congress and the Administration should act to set the right conditions for the government to adopt commercial biotechnology developments. Specifically, they should:

- **Restructure national security biotechnology programs**. While increased funding has transformed it into the leading federal agency in biosecurity research, the NIH is inexperienced and unproven in its ability to develop products. Likewise, the DHS has yet to demonstrate that it can produce cutting-edge biotechnology advances. Conversely, the DOD has significant experience and skills in developing biodefense countermeasures.

  To the maximum extent possible, research programs should be consolidated under a single agency. Where consolidation is not practical, a more effective management structure is needed to leverage the advice and expertise in different agencies in support of NIH programs.[19]
- **Encourage other countries to adopt SAFETY Act protections.** While the SAFETY Act has

16. Public Law 107–296, Subtitle G, §§ 861–865.
17. U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority, "Project BioShield," updated April 3, 2007, at *www.hhs.gov/aspr/ophemc/bioshield/index.html* (April 23, 2007; unavailable July 16, 2007).
18. James Jay Carafano, "Sustaining Military Capabilities for the 21st Century: Rethinking the Utility of the Principles of War," Heritage Foundation *Lecture* No. 896, September 6, 2005, at *www.heritage.org/Research/NationalSecurity/hl896.cfm*.
19. Martinez, "Biodefense Research Supporting the DoD," p. 26.

been successfully implemented in the United States, it does not protect companies from litigation abroad. Consequently, companies that operate outside of the United States have shied away from contributing to biosecurity because of the potential risks.

The Administration should develop a strategy to encourage other countries to adapt similar protections. The U.S. strategy should take a regional approach, beginning with the European Union and Japan.

- **Reform visa issuance and management.** U.S. national security and competitiveness rely heavily on people's ability to travel to the United States, but the current visa system is unnecessarily depriving the United States of many of the world's best and brightest scientists, students, and entrepreneurs. Long wait times for personal interviews are among the most frequently cited factors that make travel to the United States difficult.

  Congress should remove the requirement for personal interviews of virtually all non-immigration visa applicants and restore the Secretary of State's ability to waive personal interview requirements. The U.S. should begin using electronic visa applications to reduce applicants' travel expenses and should reduce processing times to 30 days or less.

  All of these reforms can be implemented in a manner that makes international travel both more convenient and more secure.[20]

Making the Nation Safer

Dual-use biotechnologies developed in the private sector offer powerful tools to protect Americans from biological threats and to increase the military's operational capabilities. Congress and the Administration should not only be aware of this growing field, but also act to ensure that the private sector—which is making the largest investment in basic research and product development—remains competitive. Specifically, the U.S. government should streamline the federal government's capability to fund and adapt new technologies, work to expand litigation protection beyond the country's borders, and further reform U.S. visa issuance and monitoring programs.

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20. James Jay Carafano, Brian C. Goebel, and Josh Kussman, "Coming to America: Initiatives for Better, Faster, and More Secure Visas," Heritage Foundation *Backgrounder* No. 1976, September 29, 2006, at *www.heritage.org/Research/NationalSecurity/bg1976.cfm*.