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New Technologies, Future Weapons: Gene Sequencing and Synthetic Biology

Ethel Machi and Jena Baker McNeill

Since the completion of the human genome project in 2003, there has been a surge of investment and discovery in both the gene sequencing and synthetic biology sectors of biotechnology. While the information contained in genome databases is not inherently dangerous, it can be used for destructive purposes. With synthesis technology becoming less expensive, more accurate, and faster every year, it is foreseeable that by 2020 malefactors will have the ability to manipulate genomes in order to engineer new bioterrorism weapons.

With every technological advancement come new national security risks. Without a clear understanding of the actual risks associated with synthetic biology, the U.S. is in danger of responding to fears with overregulation. To create regulation that fits the technology, the U.S. should fund risk assessments on the impact of synthesis and sequencing—giving policymakers a better idea of where the highest likelihood of terrorism lies. Simultaneously, and to continue leading the biotechnology revolution, the U.S. also needs to provide federal funding for synthetic biology and gene sequencing research. These steps, coupled with a strong strategy for bioterrorism that confronts issues of prevention and response/surge capacity, would allow America to reap the rewards of these emerging technologies while avoiding many of their attendant perils.

Select Agent Classifications Are No Longer Effective

In the past, one way that government agencies combated bioterrorism was by restricting access to the pathogens themselves. For instance, the Centers for Disease Control and the Department of Agriculture have worked together to regulate the laboratory use of "select agents" (pathogens and biological agents that have the potential to pose a severe threat to public health, such as the Ebola virus). But with the advent of DNA synthesis technology, simply restricting access to the actual pathogen no longer provides the security that it once did. Since the gene sequence is a blueprint, once an organism has been sequenced it can be synthesized without using samples of existing cultures or stock DNA.

In today's market it costs just a few thousand dollars to design a custom DNA sequence, order it from a manufacturer, and within a few weeks receive the DNA in the mail. Since select agents are currently not defined by their DNA sequences, terrorists can actually order subsets of select agent DNA and assemble them to create entire pathogens. The possibility for attack by a bioterrorism weapon containing a select agent will be greater in the future as synthesis technology continues to advance.

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New Restrictions and Regulations?

Since terrorists would not be able to fabricate select agents without access to the requisite genomes, it seems at first glance that restricting access to genomic databases could ameliorate much of the problem. In actuality, the gene databases are a fundamental tool for researchers. Future advances in gene sequencing and synthesis would be severely hindered by government regulation of these databases. No other area of life science depends as much on online databases. In fact, the gene sequencing and DNA synthesis fields are so database-driven that most scientific journals require genome data to be deposited into these databases as a prerequisite for publication.

Moreover, the full genetic sequence for many select agents and other pathogenic genomes (smallpox, botulism, anthrax) are already in Internet-accessible databases that currently mandate free, unfettered, and anonymous access. Once a genome has been released onto the Web, it makes little sense to restrict future publication of that genome. (Posting to the Internet is easy; removing all copies of a post is a near-impossible feat.)

Regulation Tailored to the Risks

Overregulation has a negative effect on research, while under-regulation would undoubtedly expose the U.S. to national security risks. Federal agencies such as the NIH and the NSF may be best suited to conduct ongoing risk assessments for synthetic biology and gene sequencing technologies.

As the field develops, regulations should be updated so that they can be narrowly tailored to fit the actual risks—thereby impacting future research as little as possible. In addition, independent committees of industry leaders, agency officials, and academics should be appointed to create regulations based on these risk assessments.

Staying Ahead

As the world's leader in biotechnology research, the U.S. is currently in an excellent position. However, other nations are beginning to catch up. Around the world, industry and universities alike are working to decode the genetic makeup of thousands of organisms to discover which genes are responsible for what diseases and to create technologies that perform gene sequencing and DNA synthesis faster and more accurately than ever before.

Domestic researchers need to have the funding to develop the next generation of countermeasures for genetically engineered pathogens. Without favorable legislation such as tax breaks, biotechnology companies may begin moving overseas. And without federal funding, top scientists would be unable to perform the fundamental research that will fuel the next stage of synthesis and sequencing technologies. If the U.S. is not far ahead of other nations in its research, it runs a higher risk of being susceptible to attack.

Detecting Synthetic Pathogens

As synthesis and sequencing technologies continue to advance, it will become easier and easier for rogue individuals or bioterrorists to leak man-made pathogens into water and food supplies. To mitigate this risk, the U.S. should promote research into the areas most prone to attack. Next steps should include:

- **Conducting risk assessments.** Without adequate understanding of the risks involved in any technological field, the government may overregulate and stifle scientific and technological progress.
- **Investing in biotechnology.** Other nations recognize the potential of synthetic biology. If the U.S. does not continue to invest in synthetic biology, it will technologically fall behind other countries and run a higher risk of being subjected to a bio-weapons attack.
- **Move forward with WMD Commission recommendations.** In 2008, Congress created the Commission on the Prevention of WMD Proliferation and Terrorism to study the "risk of WMD terrorism" and to recommend "steps that could be taken to prevent a successful attack on the United States." As part of this work, the commission took a close look at the threat of bioterrorism and recommended key changes that should be made to both counter and respond to such an act of terrorism. The commission focused on both surge capacity for first responders in the event of an attack and preventing would-be terrorists from gaining access to biological agents.

These recommendations would help ensure that the U.S. remains protected while working on the cutting edge of biotechnology.

Bio-Specific Strategy Needed

The WMD Commission has emphasized the need for a "bio-specific strategy" in terms of preventing acts of bioterrorism. The U.S., however, has significant work to do in terms of developing this strategy in a way that is representative of

the risk of bioterrorism, respects legitimate uses of biological agents, and prepares the nation if such a disaster strikes.

—Ethel Machi is an independent science and technology consultant and Jena Baker McNeill is Policy Analyst for Homeland Security in the Douglas and Sarah Allison Center for Foreign Policy Studies, a division of the Kathryn and Shelby Cullom Davis Institute for International Studies, at The Heritage Foundation.

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