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DISCUSSION PAPER

# Mitigating the Risks of Synthetic Biology

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## Acronyms

BGI	Beijing Genomics Institute
BWC	Biological Weapons Convention
CDC	Centers for Disease Control and Prevention
CRISPR	clustered regularly interspaced short palindromic repeats
DARPA	U.S. Department of Defense's Defense Advanced Research Projects Agency
DIY bio	do-it-yourself biology
DOE	U.S. Department of Energy
DURC	dual-use research of concern
ECDC	European Center for Disease Prevention and Control
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FMD	foot and mouth disease
G7	Group of 7
GHSA	Global Health Security Agenda
GOF	gain of function
GMO	genetically modified organism
HHS	Department of Health and Human Services
iGEM	International Genetically Engineered Machine Competition
IHR	International Health Regulations
ISIS	Islamic State of Iraq and Syria
NIH	National Institutes of Health
NSF	National Science Foundation
SARS	severe acute respiratory syndrome
USDA	U.S. Department of Agriculture
WHO	World Health Organization

## Introduction

Synthetic biology is a relatively new field that aims to make biology easier to engineer and more amenable to rational design, so that biological traits, functions, and products can be programmed like a computer. Proponents say that synthetic biology will revolutionize medicine and manufacturing. It has already been applied to the development of an antimalarial drug used in endemic regions in Africa, more rapid synthesis of flu vaccines, and the production of biofuels, detergents, adhesives, perfumes, tires, and specialized chemicals that formerly required the use of petrochemicals. As the field expands, synthetic biology may become a pervasive industrial technology, replacing chemistry in applications as diverse as mining, environmental remediation, and the manufacture and production of common household goods and foods.

However, synthetic biology may also be misused, and the advent of this technology has national security implications. The weaponization or accidental mismanagement of synthetic biological agents could result in a significant loss of life as well as ecological and agricultural damage. These scenarios of misuse would have major domestic and international repercussions; the Ebola outbreak in West Africa demonstrates that infectious diseases can have serious health consequences well beyond the pathogen's geographical origin.

To address this technology-driven global governance challenge, the United States should take preventive and mitigating action to avert and manage the potential for harmful misuse of synthetic biology technologies. However, this should be done in ways that do not compromise the United States in the legitimate application of synthetic biology and biotechnologies. By maintaining a position of technological leadership, the United States will be better able to shape the rules and norms that govern synthetic biology and its industrial applications and take advantage of the future benefits of the technology. The United States could then influence international partners to improve their regulatory frameworks, as well as institute standards to prevent and mitigate misuse.

## Reading and Writing in DNA

The tools to sequence, synthesize, manipulate, and assemble (i.e., read and write) DNA are increasingly straightforward, inexpensive, and accessible to people who are not career scientists with years of experience and advanced degrees. The ease of access to or procurement of these tools is exemplified by the International Genetically Engineered Machine Competition (iGEM). What began as an in-class competition between Massachusetts Institute of Technology students in 2003 to build simple synthetic biological systems from standard, interchangeable parts is now a major international competition. In 2010, a team from Slovenia—not among the top countries in science and engineering—won the competition, demonstrating that a few people performing at a high level in synthetic biology can outdo groups with more resources.

The excitement around synthetic biology has also generated a so-called do-it-yourself biology (DIY bio) movement, where amateurs and students tinker with living biological organisms. Community laboratories and many informal associations now exist in cities like Brooklyn, Baltimore, and Manchester, UK. The rise of DIY bio has raised concerns in the media and among policymakers, but many experts believe that amateur biologists have limited potential to do harm at this time and that there are benefits to science education and from serving as incubators for biotech companies. However, the DIY bio movement could spread to other countries as access to the technology increases.

In all, synthetic biology is increasingly accessible and affordable across a wide range of organizational structures, from individuals and small groups to large, national programs or international companies with hundreds of scientists. Future developments with direct and indirect consequences to the United States could thus come from states, terrorist groups, or even individuals. Though there are many possible beneficial uses of synthetic biology, there are two types of synthetic biology scenarios that warrant U.S. concern: biological accidents and biological weapons.

### *BIOLOGICAL ACCIDENTS*

Biological accidents occur regularly in laboratories and do not usually involve infectious organisms. When potentially infectious agents are involved, the effects are typically limited to the researchers present at the time and possibly their close contacts, and the pathogens may already be familiar to the medical community. Although accidents are unfortunate events that could have severe consequences, they do not typically result in national security concerns. However, laboratory-acquired infections with pathogens that are particularly transmissible from person to person—such as influenza or severe acute respiratory syndrome (SARS)—could have consequences that go well beyond the laboratory and national borders and could constitute a threat to national security. If the pathogen is transmissible and novel, so that there is no immunity in the population, such an accident could become a global disaster. In 1918, the naturally occurring outbreak of a novel, transmissible strain of influenza killed more than fifty million people worldwide, and the emergence of SARS caused 245 deaths among eight thousand cases in 2003, as well as a \$40 billion loss to the global economy.<sup>1</sup>

The potential for transmissible, engineered pathogens to either be intentionally misused or involved in a consequential accident sparked controversy in 2011 over gain-of-function (GOF) influ-

enza research, in which pathogens were scientifically altered to introduce traits and functions not found in the wild. Two groups of researchers in the United States and the Netherlands deliberately sought to make H5N1 avian influenza more transmissible between mammals—the function gained in this case was transmissibility—to determine how and whether this transition was likely to occur in nature and which genetic mutations would indicate that the virus was evolving to become more dangerous to humans. Although the original experiments were performed by world-class experts in world-class facilities, synthetic biology techniques could allow such influenza strains to be replicated in labs with less-robust safety systems, health monitoring, and experience.

In October 2014, the White House and the Department of Health and Human Services (HHS) announced a pause in U.S. funding of GOF research to allow for a detailed review and subsequent policy development, a process that is projected to be completed in one year.<sup>2</sup> Still, GOF research is likely being performed in well-known influenza laboratories outside of the United States, including in the Netherlands, Italy, United Kingdom, Germany, Canada, China, Hong Kong, and Japan. There are no barriers to other laboratories anywhere in the world participating in this type of research.

The accidental release of a biological agent with synthetic components could also harm the environment; likewise, some “outside the laboratory” applications of synthetic biology could have unintended consequences. For example, some scientists have proposed changing the DNA of mosquitoes to make them resistant to malaria using a newly developed gene-editing technique, clustered regularly interspaced short palindromic repeats (CRISPR), which allows sections of DNA to be searched for and replaced in a matter roughly analogous to editing a document in a word processor.<sup>3</sup> Large numbers of engineered mosquitoes would be released to mate with the malaria-sensitive population, resulting in malaria-resistant offspring, which would pass along malaria resistance. Such a project has the potential to decrease the prevalence of malaria, a disease which currently kills more than six hundred thousand people—mostly children—per year. Yet, the resistance genes could potentially drift to other species, causing unknown and hard-to-reverse consequences to other species and to the environment. Other synthetic biology applications in mining, bioremediation, pollution detection, and agriculture pose similar risks.

## *DEVELOPMENT AND USE OF BIOLOGICAL WEAPONS*

Nations, well-resourced terrorist groups, and technically proficient individuals already have many easier options to produce biological weapons without synthetic biology; human pathogens that could be weaponized are prevalent in nature and can also be found in laboratories around the world. Technologies to cultivate and weaponize many of these pathogens have been available for decades. Once an actor—state, nonstate, or individual—has the capability to make a biological weapon, it could be produced in practically unlimited quantities. However, synthetic biology, GOF research, and the increasingly simplified techniques associated with manipulating genes can increase the types and accessibility of biological weapons, which could be exploited by both state and nonstate actors.

With synthetic biology, it is no longer necessary to isolate a pathogen either from nature or a sick patient before developing it as a weapon. The ability to recreate a pathogen from scratch allows eradicated or difficult-to-access pathogens—including smallpox, which has been eradicated from nature although its genetic sequence is freely available online—to be used as weapons. Even viruses that are not eradicated and could theoretically be isolated from the environment, including the Ebola or foot and mouth disease (FMD) viruses, may require nefarious actors to take steps that could compromise their opera-

tional security; it might be easier to synthesize these organisms from scratch. A skilled actor could use synthetic biology to develop novel pathogens (e.g., a variant of influenza). Finally, synthetic biology could also allow pathogens to be modified so that stockpiled medical countermeasures, diagnostic tests, or detectors are rendered ineffective, leading to delays in diagnosis and public health interventions.

There have been scientific gains in microbial forensics to determine the source of a microbe. For example, a specific strain of anthrax found in a U.S. army laboratory was tied to anthrax included in letters sent to several congressional offices in 2001. Still, it is difficult to attribute a biological attack or even definitively declare that a disease outbreak is the result of an attack. Due to the ambiguity of attribution, biological attacks for commercial gain may become more attractive as technical skills proliferate. For example, a deliberate outbreak of a crop-killing fungus, or the introduction of FMD in a nation that formerly held FMD-free status, would harm that country's economy. Billions of dollars would need to be spent on culling infected and potentially infected animals, as well as vaccination programs, and there would be a revenue loss for red meat exports until FMD-free status could be regained.

## Strategic Surprises

It is likely that the United States would be surprised by the misuse of synthetic biology. Unsafe practices—such as performing work on contagious, modified pathogens in inappropriately low levels of containment—can occur anywhere, and improper training could result in a breach of containment even in well-equipped laboratories performing routine research on pathogens. In the summer of 2014, for example, a breach of protocol potentially exposed sixty-one staff members of the U.S. Centers for Disease Control and Prevention (CDC) to anthrax.<sup>4</sup>

Data regarding the prevalence of laboratory accidents is largely unavailable and would not serve as a warning indicator for future accidents. Also, there are few incentives to report accidents as it is embarrassing to the laboratory workers and to the research institution; exposures are often caused by failure to follow standard protocols. In the United States, as a result of the CDC's Select Agent Program, potential and actual exposures to a list of pathogens are reported to the CDC and U.S. Department of Agriculture (USDA), but this is the exception. To acquire more data about biosafety lapses, researchers would need to be able to blamelessly report such exposures, in a system modeled after the aviation industry, where there are incentives to provide data on safety incidents.

Regarding the potential to produce synthetic biological weapons, there are no reliable, accurate warning signs that could alert the United States to a growing danger from deliberate misuse of synthetic biology. Unless an informant or defector released a report, or a state or group openly declared its intention to weaponize synthetic biology, there would be no obvious external indicators of such activity. Past cases illustrate how difficult it has been to detect biological weapons development. For instance, there were few indications during the Cold War that the Soviet Union employed tens of thousands of scientists dedicated to making biological weapons or that Iraq was developing biological weapons at the time of the first Gulf War. Actual and attempted biological attacks, including those perpetrated by the Rajneesh cult in Oregon in 1984 and Aum Shinrikyo in Japan in 1995, were not discovered until after the fact. Even when information is acquired that points to a specific interest in developing biological weapons, there is still a great deal of uncertainty about whether this amounts to a committed effort. For example, a laptop belonging to a member of the Islamic State of Iraq and Syria (ISIS) was found to contain instructions in Arabic for weaponizing bubonic plague isolated from infected animals. However, the operational threat posed by this information remains unknown. Likewise, tactical warning regarding a potential biological weapons threat is also difficult to achieve, simply because so much of biology is dual use and facilities designed for vaccine production or other beneficent purposes can be easily converted to produce weapons.

## Implications of Either Deliberate or Accidental Misuse

The accidental or deliberate misuse of synthetic biology would have profound implications for U.S. interests. The most obvious is the potential loss of American lives. Depending on the specifics, there could also be ecological and environmental damage, such as the destruction of an agricultural commodity, which could have serious economic consequences and could damage quality of life in the affected areas. Though hard to assess, public confidence in the U.S. government might also be severely compromised if the government was viewed as slow and ineffectual or as having failed to take necessary precautions.

Even where the physical consequences of either scenario are comparatively small or localized, the subsequent response could still prove costly. If an accident occurred in the United States or a terrorist attack originated in a U.S. research institution, the entire U.S. research enterprise would be vulnerable to regulations that may not be appropriate or effective, but rather enacted solely to address congressional and public concern. This occurred after the anthrax letter attacks in 2001; several regulations put into place were security improvements, but others made research on a select group of pathogens more difficult, expensive, and slow, without compensating security or safety benefits.

If either scenario occurred overseas, the implications for U.S. interests would be similar. U.S. citizens and property could be harmed and the U.S. government would almost certainly feel compelled to respond. Depending on the scale of the incident, the costs could be substantial. And if a treaty ally were the victim of a biological weapons attack, the U.S. government would be obliged to defend it against further attack, much as it would in any other case.



## Preventive Options

Complete prevention of the accidental or deliberate misuse of synthetic biology is not possible. However, the level of risk can be reduced and preparations can be made to diminish the consequences.

Regarding accident prevention, laboratory safety can be improved and better enforced, and standards can be promulgated internationally. There is now adequate guidance for laboratories to develop oversight systems to catch and contain accidents, but not all research institutions adhere to such guidance, require adequate training, or have sufficient resources to dedicate to biosafety. There is also great variability from one research institution to another, even within a nation. Implementing nationwide biosafety norms could begin to address this deficit. For example, it would be helpful to know that GOF research is performed with sufficient safety systems in place, including national standards for equipment maintenance, worker safety training, health monitoring, surveillance, and other measures to help keep researchers and the public safe. It would be ideal to promote such safety standards for all laboratory work to protect workers everywhere. However, confining norms to research with the potential for international consequences, more often performed in donor nations, would allow routine medical work and public health diagnoses to continue even in less-resourced environments. Without nationwide standards for biosafety, organizations will remain reluctant to commit the resources required to achieve high levels of biosafety.

In the last decade, amateur biology, or DIY bio, has gained popularity. Although DIY bio may not require specific regulation now, the situation is likely to evolve, so mechanisms to improve the safety and knowledge of the DIY bio community's activities may help to prevent either an accident or misuse of DIY laboratories to develop a weapon. There is an "ask a biosafety expert" program, funded by the Alfred P. Sloan Foundation, for DIY bio enthusiasts to tap volunteers from the American Biological Safety Association to provide advice, and there are various codes of conduct. For the iGEM competition, teams have to complete safety forms for their projects and biosecurity experts are involved in the judging. For the last five years, a successful Federal Bureau of Investigation (FBI) outreach program has been working with DIY bio practitioners to raise their awareness of potential misuse and to give them points of contact to report suspicious behavior. These mechanisms can forestall an incident and generate law enforcement awareness of potential malign actors.

Another preventive measure to consider is a review of regulations to determine if specific synthetic biology applications have adequate oversight from the appropriate federal agency. There appear to be gaps and a need for updating; a 2013 fundraising campaign on Kickstarter caused consternation by producing glowing plants and distributing seeds to more than eight thousand supporters. The mechanisms used to produce the plants, distribute them, and plant them do not violate any current rules or regulations; however, allowing glowing plants to be introduced into the environment without regulatory review struck many scientists as inappropriate. Congressional action will be necessary to expand and update regulatory authority for the USDA and the Environmental Protection Agency (EPA) to appropriately regulate modern methods to alter plant genomes.<sup>5</sup>

There are already mechanisms in place that can be expanded to cover the potential use of synthetic biology for weapons. Many gene synthesis companies adhere to a code of conduct and screen customer orders for pathogen matches, according to U.S. Department of Health and Human Services guidance. There are no options for the United States to impose regulations on international companies that do not screen orders, but actions can be taken to encourage other nations to issue similar guidance, promote industrywide screening standards, and champion a common code of conduct.

The United States also participates in international agreements that prohibit biological weapons development and use, especially the Biological Weapons Convention (BWC). Critics point out that the treaty does not have a verification mechanism and that it has been violated several times in the past, most notably by the Soviet Union. However, the dual-use challenges of biology make a verification mechanism unfeasible. The treaty has effectively reinforced the norm against biological weapons and served as a vehicle to discuss other issues, such as the potential for biological accidents or the misuse of synthetic biology. UN Resolution 1540, another legally binding mechanism, requires nations to have and enforce measures against the proliferation of nuclear, chemical, and biological weapons. The U.S. Cooperative Biological Engagement Program assists partner nations in fulfilling their Resolution 1540 obligations and boosting their public health infrastructure to mitigate biological incidents.

## Mitigating Options

Given the difficulties in preventing a biological incident of any type, the main goal of contingency planning should be to mitigate an event whether it is deliberate, accidental, or a naturally occurring disease—which may be difficult to distinguish at first.

Biological incidents are different from other types of attacks; a prepared, efficient response may limit the size and scope of an attack by orders of magnitude by reducing the attack's consequences. Even noncontagious diseases spread their consequences, as victims travel from the site of infection to be hospitalized elsewhere, so it is important that disease detection and response is effective at its source in order to limit the size of an outbreak. As has been demonstrated clearly in the 2014 West Africa Ebola epidemic, fighting a disease outbreak is similar to fighting a fire: it is easier to contain and extinguish if it is small. If those early days are lost to inaction, the lives, effort, and resources required to quell it grow exponentially.

There are two main efforts in place that draw attention to the need to boost public health infrastructure and response internationally. The World Health Organization (WHO) established the International Health Regulations (IHR), which aim to protect against the spread of epidemics and other public health emergencies across national borders and to limit international interference with travel and trade. The WHO also published a monitoring tool for IHR compliance, so that nations could self-assess their progress in core public health capacities such as surveillance, response, preparedness, and risk communication. Yet in 2012, less than 20 percent of nations reported IHR compliance, leaving open the possibility that the world will face multiple Ebola-like epidemics should disease strike the underprepared.

The dismal implementation of IHR standards was a factor behind the creation of the Global Health Security Agenda (GHSA) launched in February 2014 by the White House, in partnership with more than twenty-five other governments, the WHO, and other international organizations. The GHSA aims to organize efforts for donor countries to improve public health infrastructure, biosafety, and security in nations struggling to implement the IHR. The GHSA is rightly agnostic about the origin of biological threats, as the same public health infrastructure improvements are necessary in order to respond to all biological incidents, whether deliberate, accidental, or natural. It is too early to tell if the GHSA will succeed in focusing and coordinating efforts to build public health infrastructure, but the 2014 Ebola outbreak is a clear reason to continue a large, international effort to boost public health infrastructure where it is weakest, as all nations depend on a swift response to potential pandemics.

## Recommendations

It is challenging to prevent accidental or deliberate misuse of synthetic biology, especially given its global accessibility and relatively low costs. It is also impossible for the United States to remain a leader in synthetic biology development by as great a margin as it is currently given the investments of nations hoping to tap into the potential economic, medical, and manufacturing benefits of synthetic biology research. However, the United States can take steps to maintain its technological leadership, prevent many dangerous scenarios, and mitigate consequences of misuse. The United States can make progress toward these ends by implementing the following domestic and international recommendations.

### DOMESTIC RECOMMENDATIONS

- *Establish a system within the CDC to increase biosafety reporting and learn where there are weaknesses in protective equipment or training.* Beyond work with regulated pathogens, there is a lack of information about biosafety incidents and potential exposures. This not only prevents safety best practices from being developed and promulgated; it is also dangerous if potentially serious biosafety lapses are not reported. The CDC should develop a biosafety reporting system modeled after the incident reporting in the aviation industry, where operational experiences and incidents may be reported without fear of punitive action. In such a system, the CDC would analyze mistakes without attributing them to individuals, except when incidents are the result of criminal conduct.
- *Extend biosafety and biosecurity beyond traditional laboratories, focusing on DIY bio groups, iGEM, and other potential amateur uses of synthetic biology.* As the current funding source for the “ask a biosafety expert” initiative will soon cease, HHS should allocate resources to continue these programs. This program may be expanded by land grant universities, as it is part of their mission to provide public access to their expertise. The FBI’s successful outreach program to DIY bio practitioners to raise their awareness of potential misuse and give them points of contact to report suspicious behavior should be extended, as these outreach mechanisms can forestall an incident and generate law enforcement awareness of malign actors. Given that DIY bio is a global phenomenon, the model that the FBI has built in the United States should be a model for other nations and should be promulgated through an FBI partnership with Interpol.
- *Extend research efforts beyond the U.S. Department of Defense’s Defense Advanced Research Projects Agency (DARPA) into other U.S. government scientific-funding streams, such as the National Institutes of Health (NIH), National Science Foundation (NSF), and Department of Energy (DOE), to ensure their complete development and application.* Although DARPA is pursuing a number of technical solutions to make synthetic biology safer, less amenable to misuse, and easier to attribute, including developing intrinsic biosafety systems so that organisms cannot survive outside of a laboratory environment, these research efforts by themselves are not enough and should be sustained beyond the initial development period by other U.S. government agencies that fund research in synthetic biology, especially the NIH, NSF, and DOE.

- *Clarify and update regulations and oversight with agencies that oversee synthetic biology applications, particularly the EPA, the Food and Drug Administration (FDA), and the USDA.* The fact that seeds producing glowing plants can be distributed to thousands of people across the United States without regulatory review by the EPA, FDA, or USDA reveals that regulatory oversight needs to be updated. Though agencies can make some changes to these rules, congressional action will be necessary to expand and update regulatory authority for the USDA and EPA to appropriately control modern seed and plant products.
- *Refocus regulations on specific applications of synthetic biology, rather than trying to delineate or regulate the entirety of the field, to encourage innovation within the United States.* The example of how GMOs became a public policy issue in the EU should serve as a warning to the United States. The prohibition on GMOs in the EU decreased profit margins for European farmers by up to a billion dollars each year; the extra regulations for bioscience research have direct and indirect costs for EU science. Instead of a broad-brush ban of the entire field, it is the specific products made using synthetic biology that should be regulated, whether they are detergents, vaccines, or seeds.

#### INTERNATIONAL RECOMMENDATIONS

- *Make biosafety a nation-level problem, particularly for donor nations that are funding research with the potential for consequential accidents.* Biosafety is often not perceived as important enough to afford resources dedicated to training, oversight, equipment, standards, and other mechanisms to protect the public's health—even in donor countries. The ongoing U.S. process to evaluate the risks of GOF research provides an opportunity to precisely define what biosafety systems are critical, as well as what national oversight mechanisms for biosafety instruction and compliance are necessary. Once defined, the CDC and NIH should work with the WHO and European Center for Disease Prevention and Control (ECDC), as well as nations that fund GOF work, including China, to promulgate a set of biosafety norms that allows for necessary biomedical research with appropriate safeguards. This would include laboratory accident reporting, biosafety instruction, accreditation, and requirements for biosafety oversight.
- *Expand gene-synthesis screening—the customer and sequence screening performed by companies to determine that no dangerous pathogens are being requested for synthesis—to more countries and more companies.* The United States should reach out to other nations, especially China, to produce guidance similar to the 2010 U.S. Health and Human Services recommendations for sequence screening, increase the number of companies that perform gene screening, promote awareness of companies' codes of conduct, and encourage providing those companies with a means to report a suspicious order. The Biological Weapons Convention meetings, held twice a year in Geneva, could be one of several forums at which the United States works with other countries to enact similar screening measures.
- *Improve public health infrastructure internationally, so that IHR compliance worldwide is significantly higher than 20 percent.* The 2014 Ebola crisis in West Africa is a clear example of what can happen when an infectious disease outbreak is not contained by all of the elements of a public health infrastructure, including surveillance, contact tracing, and monitoring. Severe budget cuts to the WHO have hobbled its disease response, worsening the problem. Synthetic biology may pose particular problems that make public health responses more challenging in the event of an accident or intentional use, but there remains a severe deficit of public health infrastructure to deal with even natu-

ral diseases. The GHSA, which was conceived for this purpose, has been endorsed by the Group of Seven (G7) in June 2014, and the United States has pledged to help thirty countries meet GHSA objectives over the next five years. The process of building public health infrastructure will take longer than five years, however, so it will be important for future administrations to continue to support the GHSA and other global health programs within the Departments of State and Defense.

## Conclusion

There is a great deal of uncertainty about the future of synthetic biology. Some people believe that the advent of synthetic biology will lead to dramatic changes in medicine, agriculture, and industries that currently rely on petroleum. Others believe those changes are likely to be incremental. Nonetheless, the technology to manipulate genomes, which is already substantially influencing the role of medicine and agriculture in national security, may not always be used for beneficial purposes. Though the United States has limited ability to stop the intentional use of synthetic biology in a biological weapon, and biological accidents, there are numerous options available to mitigate the serious consequences that could result. In all cases, the United States should carefully balance its efforts to prevent and mitigate the harmful effects of synthetic biology with its support of such research and related technologies. Not only are the potentially wide-ranging benefits of synthetic biology at stake, including to the U.S. economy, but so is the ability to promote regulations that could make the technology safer for everyone.

## About the Author

**Gigi Kwik Gronvall** is a senior associate at the University of Pittsburgh Medical Center (UPMC) Center for Health Security and associate professor of medicine and public health at the University of Pittsburgh. She has published and lectured extensively on issues such as laboratory security and personnel security, the need for and process of procuring medical countermeasures, the management and governance of dual-use biological advances, and the approach the United States should take to ensure national security while promoting new advances in biotechnology. Gronvall is the author of the book *Preparing for Bioterrorism: The Alfred P. Sloan Foundation's Leadership in Biosecurity*. She is working on a second book about the governance and risks of synthetic biology.

Gronvall is a member of the Threat Reduction Advisory Committee, which provides the secretary of defense with independent advice and recommendations on reducing the risk to the United States, its military forces, and its allies and partners posed by nuclear, biological, chemical, and conventional threats. She served as the science advisor for the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism from April 2009 until the commission ended in February 2010. Gronvall was selected to join the EU Visitors Program in 2011, a competitive process designed to increase mutual understanding between professionals and future leaders from non-EU countries and their EU counterparts. Prior to joining the UPMC in 2003, she worked at the Johns Hopkins University Center for Civilian Biodefense Strategies, which she joined in 2001. From 2000 to 2001, she was a National Research Council postdoctoral associate at the U.S. Army Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland. Gronvall received a BS in biology from Indiana University, Bloomington. She subsequently worked as a protein chemist at the Memorial Sloan-Kettering Cancer Center and received a PhD from Johns Hopkins University for work on T-cell receptor/MHC I interactions.



## Endnotes

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1. Jeffrey K. Taubenberger and David M. Morens, "1918 Influenza: The Mother of All Pandemics," *Emerging Infectious Diseases* 12, no. 1, January 2006, pp. 15–22; Jong-Wha Lee and Warwick J. McKibbin, "Estimating the Global Economic Costs of SARS," in Stacey Knobler et al., eds., *Learning from SARS: Preparing for the Next Disease Outbreak*, Institute of Medicine (Washington: National Academies Press, 2004).
  2. *White House Office of Science and Technology Policy Blog*, "Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research," October 17, 2014, <http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>.
  3. Kenneth A. Oye et al. "Regulating Gene Drives," *Science* 345, no. 6197, August 8, 2014, pp. 626–28.
  4. "Report on the Potential Exposure to Anthrax," Centers for Disease Control and Prevention, July 11, 2014.
  5. Sarah R. Carter et al., "Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options," J. Craig Venter Institute, May 2014.

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