Renovating Governance Strategies for Synthetic Biology and Other "Dual-Use" Technologies**

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Summary

The life sciences offer tremendous societal benefits and are diffusing worldwide, but this scientific revolution carries potentially devastating risks. Synthetic biology has opened the door to *de novo* assembly of appalling contemporary pathogens and those responsible for eradicated diseases, such as smallpox, while other vanguard life sciences technologies could be hijacked to manipulate the human immune, nervous, and endocrine systems. Some gene synthesis companies have voluntarily taken steps to prevent the rogue assembly of dangerous pathogens by screening customers and orders for genes. Similarly, after the September 11th attacks, the Federal Bureau of Investigation (FBI) forged a public-private screening partnership with manufacturers of various "dual-use" goods and services that could be diverted from legitimate purposes to cause harm, a quietly effective tool in efforts to disrupt and prosecute terrorist and criminal activities. Government and academia, respectively the traditional guarantors of national security and fountains of innovation, will be hard-pressed to keep pace with the life sciences revolution and fashion new governance approaches. If industry more fully enters the nonproliferation fray, society will have better leverage to keep one step ahead of the bad guys.

Current realities

Assuring the security of a state is traditionally a government responsibility, one that justifies armed forces, the cultivation of trading partners, military alliances, intelligence, diplomacy, and the negotiation of treaties to draw behavioral boundaries and cement common interests. Industry's customary role vis-à-vis security is to supply material to a state's armed services or to comply with regulations on the manufacture and sale of product(s), including the declaration of activities deemed pertinent to treaty-controlled weapons systems, such as the production of chemicals that are precursors to warfare agents, and the acceptance of inspections to ascertain treaty compliance. Individual governments can also stipulate the review and licensing of weapons-critical products before sales to countries of proliferation concern. In addition, major supplier nations have harmonized export controls on numerous items via the Australia Group, the Nuclear Suppliers Group, and the Missile Technology Control Regime. Thus, for the most part, industry is reactive when it comes to nonproliferation.

Decades ago, the pace of discovery in the life sciences began ramping up with the emergence of molecular biology, cell biology, and genomics. The discovery rate turned revolutionary with the convergence of life sciences, engineering, the physical sciences, and information technology, giving rise to entirely new disciplines, including synthetic biology. With promising new applications in health, energy, agriculture, and the environment that will elevate the quality of life and drive economies, the life sciences are diffusing worldwide. Nations with flourishing biotechnology industries or that are laying the foundation to become biological powerhouses include Brazil, China, Cuba, Egypt, India, Mexico, Russia, Singapore, South Korea, and Taiwan. Furthermore, automated equipment that "de-skills" previously labor-intensive techniques and processes is enabling those with rudimentary science know-how to perform advanced life sciences work. These circumstances expose serious vulnerabilities in traditional government-designed nonproliferation tools.

Following in the footsteps of the military, which of necessity became a path-breaker in technology and societal change, large companies have also taken on unanticipated roles as they expanded

operations across multiple borders. Accordingly, in 2010, the International Standardization Organization issued ISO standard 26000, which lists six pillars of corporate responsibility: consumer issues, fair operating practices, the environment, labor practices, human rights, and community involvement and development.

Scientific opportunities and challenges

The benefits of the life sciences aside, panels of distinguished scientists have recognized the challenge of preventing the abuse of vanguard life sciences technologies, such as RNA interference and nanobiotechnology. To illustrate, malicious actors could combine sophisticated targeted-delivery technologies with bioregulators to manipulate the human immune, nervous, and endocrine systems. Synthetic biologists have artificially created the polio and 1918 influenza viruses, which crippled and killed tens of millions in the 20th Century, and recovered Marburg, a hemorrhagic fever virus, from a full-length cDNA clone. In 2010, scientists required 1,080,000 base pairs, which cost a few dollars apiece, to generate the Mycomplasma genome *de novo*. Variola major, the virus that causes smallpox, has a comparatively modest number (186,102) of base pairs, which can be purchased for a few dollars apiece. Synthetic biology has opened the door to the assembly from scratch of appalling contemporary pathogens as well as those responsible for eradicated diseases. Such factors prompted geneticist and molecular biologist Matthew Meselson to warn in 2000 that, in the hands of those with malevolent intent, new life sciences knowledge and technologies present "unprecedented opportunities for violence, coercion, repression, or subjugation."

Responding to the potential misuse of synthetic biology, the companies of the International Association of Synthetic Biology and the International Gene Synthesis Consortium have voluntarily fashioned safeguards to prevent the rogue assembly of dangerous pathogens. They are screening orders for genes to ensure they will not add up to something dangerous like anthrax, and they are screening customers to check that they are affiliated with legitimate scientific enterprises and have no criminal histories or terrorist associations. To screen customers, gene synthesis companies are accessing various government-compiled "bad guy" lists, such as the United States' Specially Designated Nationals, Denied Persons, and Statutorily Debarred Parties lists and Germany's Handbook of Export Controls list.

This screening activity mirrors a public-private partnership initiated after the September 11th attacks, when the FBI reached out to manufacturers of "dual-use" goods and services that could be diverted from legitimate purposes to harm U.S. citizens and property. Neither the FBI nor the companies want to see such products hijacked for terrorist or criminal purposes. Moreover, each partner has something the other wants. Governments want to halt proliferation, and the companies, which may be contacted by aspiring proliferators, have information useful in that quest. Governments, which devote staggering resources to identify terrorists, front companies, black marketeers, organized criminals, among other unscrupulous types, have databases that can help companies avert ill-advised sales. Thus, mutual interests and needs forged common sense partnerships wherein corporations notify the FBI of suspicious sales requests so that questionable customers could be screened against its databases. This quiet practice currently involves hundreds of businesses, including chemical and internet companies, resellers of dual-use equipment, and agricultural goods and services firms. Annually, the FBI receives thousands of notifications of suspicious activity that enable law enforcement authorities to disrupt and prosecute terrorist and criminal activities. This experience proves that voluntary data sharing can help thwart the acquisition of dual-use goods for malicious purposes.

Policy issues

The main international barrier to the spread of germ weapons is the Biological and Toxin Weapons Convention, which lacks verification measures to unmask state-level bioweapons programs. Impediments to the misuse of synthetic biology by nonstate actors are similarly wanting. The sentinels on alert for angry spouses, disgruntled employees, and terrorists with biological mayhem in mind, namely, local law enforcement officers, have no training to recognize the Nipah virus, for example, much less to be able to spot someone trying to synthesize this killer. Thinking about how to govern the life sciences and other fast-moving areas of technology needs to be jump-started:

- Governance is lagging behind the life sciences revolution, in part because policy makers, challenged to follow technical developments in this arena, are not well-suited to devise governance approaches. These circumstances do not presage government as the incubator of new, effective life science governance measures, nor are there favorable odds that the international community can agree on control measures, which would be less effective unless universally applied. Moreover, another traditional wellspring of invention, the academic community, is unlikely to widely support new life sciences controls, which are seen as conflicting with academic freedoms.

- Whether the perpetrator is a state, group, or lone-wolf actor, today's advanced technologies could facilitate acts that cause horrific death tolls and massive economic and societal disruptions. A seventh pillar of corporate responsibility is needed: industry best practices to prevent the diversion of products for malevolent purposes.

- In the end, industry may be the best engine for fresh, effective self-regulation and, when needed, carefully balanced regulation in the life sciences. Private sector scientists, savvy in both the technological developments and business trends, are well positioned to identify choke points, tactics, and avenues to prevent misuse of the life sciences. Governments should incentivize life sciences companies to participate in the governance discussion.

- Only the exigent circumstances of September 11th gave rise to the voluntary data sharing program, which the FBI has not exported. This type of public-private nonproliferation partnership is more broadly applicable to other sensitive technologies, equipment, and materials. For starters, the U.S. government should lobby nations that are major suppliers of advanced technologies to adopt this model.

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