COUNCIL on FOREIGN RELATIONS

POLICY INNOVATION MEMORANDUM NO. 38

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Re: Making the New Revolutions in Biology Safe

The foreign policy community has largely ignored the unfolding revolution in biology, leaving its supervision to traditional scientific bodies, and, in rare cases, law enforcement agencies. This is a tremendous mistake. New technologies and genetic tools now allow biologists to manufacture living organisms, give viruses and bacteria capacities not found in nature, and push the boundaries of evolution in ways unimaginable less than a decade ago. Moreover, the costs of genetically decoding and modifying pathogens have plummeted since 2000, from billions of dollars to only a few thousand. Policymakers urgently need to work with diplomatic, law enforcement, disease surveillance, and global trade leadership worldwide to simultaneously regulate and deter malevolent or careless abuse of the new biology, while promoting its beneficial applications to medicine, science, and technology innovation.

THE NEW REVOLUTIONS IN BIOLOGY

Two revolutions are unfolding in biology, giving scientists the ability to turn existing germs into more dangerous ones with gained functional characteristics, and to synthesize new life forms entirely. The gain-of-function (GOF) revolution has been brought starkly to light by recent influenza experiments. Fearing various forms of bird flu viruses might naturally evolve into pandemic strains that could kill millions of people, the Animal Influenza Lab of China's Harbin Veterinary Research Institute used new biology techniques in 2013 to manufacture 127 previously nonexistent types of influenza viruses, five of which spread through the air between guinea pigs, indicating they might transmit casually from person to person. The Chinese virus-makers were not the first to manufacture killer microbes for the ostensible purpose of imagining what could emerge from natural evolution. In 2012, scientists in Wisconsin and the Netherlands manipulated the genes of H5N1 bird flu viruses, turning what in nature are bird-to-bird influenzas into forms of the virus that could spread through the air between ferrets—lab stand-ins for human beings.

A second revolution—synthetic biology—exploits gene-sequencing technology that makes it cheap, fast, and easy to decipher DNA codes. Companies offer "bricks," or sections of genetic sequences, which can be purchased to build novel genomes, like stacking Legos. With GOF and synthetic biology, scientists are no longer mere observers of life but its

creators, engaged in a cheap, fast-paced, multinational collaboration that is decoding all life forms, identifying their interesting "bricks," and exchanging them in real time, via the Internet.

THE UNFOLDING PROBLEMS

While the new biology is racing pell-mell into a twenty-first century of biocreation, national and international surveillance and regulatory systems are bogged down in an outdated disease and counter-bioterrorism approach, focused on old-fashioned "select agent" lists of germs and toxins. Since the anthrax mailings of 2001, the U.S. Congress has appropriated hundreds of billions of dollars to develop technologies aimed at such antiquated lists. Meanwhile, the private sector worldwide is largely unregulated and unobserved. The U.S. and Dutch GOF flu experiments spawned debate between virologists and experts in public health and biosecurity, resulting in a set of U.S. National Institutes of Health guidelines for dual-use research of concern (DURC) on avian influenza. But as the Chinese creation of flu viruses demonstrates, unilateral U.S. guidelines offer no protection against overseas synthesis of dangerous new life forms. Moreover, U.S. biologists argue that domestic "overregulation" of GOF and synthetic biology work puts the country at an economic and scientific disadvantage compared to competition in Europe, Asia, and Latin America.

DURC poses some immeasurable, but potentially high-impact, threats for state or nonstate terrorism. The more immediate risk is the unintended release of pathogens, with potential to harm humans, livestock, agriculture, or the environs. There is negligible oversight in any country over potential DURC executed in low-security labs, such as those found in high schools, colleges, and most private sector facilities. Since 9/11 there has been an exponential proliferation of biosafety level-3 (BSL-3) and -4 (BSL-4) laboratories worldwide—by definition, DURC-potential facilities—in which special pathogens, such as killer influenzas, Ebola, and smallpox, are stored and studied. Since 2003, more than one hundred human-exposure accidents involving deadly microbes have occurred in such U.S. labs. No uniform international or regional standards or definitions exist of laboratory security, safety, or protocols for DURC.

WHAT NEEDS TO BE DONE

There is no consensus among science and security experts regarding which dual-use research weighs on the side of social benefit, versus that which poses significant danger to mankind. If left to self-supervise, scientists typically opt for a deregulated working environment. But policymakers need to reframe the issue and not leave risk assessment and response solely in the hands of the scientific community. Policy recommendations include the following:

- *The U.S. Department of State (DOS) and the Department of Health and Human Services (HHS) should collaborate with international partners to harmonize global laboratory and biosecurity standards.* DOS and HHS should work closely with the European Union, Organization of American States, African Union, and Association of Southeast Asian Nations to promulgate clear definitions of BSL-3 and BSL-4 labs, standards for biosecurity, pathogen storage, limits on GOF research, and screening of shared novel genetic sequences. Setting equivalent regulatory standards worldwide will minimize the risk that one well-regulated country's scientific pursuit is stifled while another's surges forward in the absence of government caution. A model for emulation might be the Codex Alimentarius, established by the Food and Agriculture Organization and the World Health Organization (WHO) in 1963 to standardize all food-safety guidelines worldwide.
- *The Centers for Disease Control and Prevention (CDC) and the FBI should shift away from a "special pathogens" approach to one of monitoring and enforcement.* A select-list approach offers false security, and by definition misses all novel threats. The CDC and FBI should work closely with the WHO, Interpol, the European Center for Disease Control, and analogous agencies worldwide to identify who is working on newly created or genetically augmented organisms, and to assess their threats. The Biological Weapons Convention process can serve as a multilateral basis for this conversation, but discreet, bilateral, and regional discussion is likely to prove more fruitful.

- *The Department of Commerce, Animal and Plant Health Inspection Service (APHIS), and the Office of the U.S. Trade Representative should create a regulatory framework appropriate to the DURC conundrum*. In an era when emailed gene sequences render test-tube transport obsolete, the proper boundaries of export are difficult to define. Overregulation risks stifling science. A model for regulation might draw from the experiences of the International Plant Protection Convention and APHIS' engagement via the agency's International Services. Many nucleotide distribution centers already monitor "sequences of concern" for Internet traffic in genomes, demanding special information on individuals seeking pathogen-related genetic details—an approach that should be embraced for government application.
- *Private biotech companies and "biobrick" distributors should assign biosecurity tags to all man-made products*. Trade in genomic sequences should be transparent and traceable, featuring insertion of nucleotide tags that can be monitored. Tagging is already mandated for genetically modified crops, and it can be implemented for man-made or commercially traded significant biobricks. The industry should self-finance necessary monitoring and enforcement of standards of practice, and permit unrestricted government inspection in the event of breakdowns in biosafety or lab security.
- *Congress should restore disease-surveillance and response funds to the CDC and the U.S. Department of Agriculture (USDA)*. Such funds to the CDC have been cut by 25 percent—about $1 billion—since 2010 and further diminished by 5.1 percent under sequestration, including the loss of fifty thousand state, territorial, city, and county public health officers. CDC and USDA have been cut so severely that they have no reprogrammable funds. Both organizations should have sufficient funding and scientific capacity to ensure that if a pathogen is deliberately or accidentally released, systems of identification, containment, and response are in place that can eliminate or minimize the risks to humans, livestock, crops, and the environment. Any cost-benefit analysis strongly supports these modest expenditures, as release of foot-and-mouth disease would cost the U.S. livestock industry $14 billion a year; GOF research is calculated to increase the risk of human infection two-hundred-fold; and the World Bank estimates a virulent influenza pandemic would cost the world economy $3 trillion.
- *The United States should fund the WHO's response capacity, leading a donor $100 million annual special support for the next five years.* Facing tough budgetary constraints, the WHO has cut its 2014–2016 crisis-response budget by more than half and shifted outbreak responsibilities to the country level. But only thirty-five countries meet surveillance-capacity standards set by the International Health Regulations. The WHO's World Health Assembly of 194 nations aspires to country self-reliance in IHR compliance, but a bridge in support is needed to get poorer nations to that goal, and keep the WHO disease response program alive. The United States should take the lead; pick up most of that $100 million tab for FY14, rally other wealthy public donors and commit to provision of a portion of the bridge funds thereafter, diminishing annually as self-reliance grows, and zeroing out by the end of 2019. At no additional cost beyond restoration of now-sequestered monies, Congress should sustain the U.S. Agency for International Development PREDICT Project, which has trained fifteen hundred people worldwide to date and discovered two hundred previously unknown viruses.

In general the academic, institutional, and commercial science sectors bridle at all forms of external regulation and argue that outsiders cannot comprehend their needs, innovations, and safety measures. As with genetic engineering in the 1970s and nuclear physics in the mid–twentieth century, scientists are wrong to insist that general society has no right to be wary of their efforts, or to insist on oversight. Concerns in poorer countries that the United States and Europe will use DURC regulation to hold them back are not entirely groundless. It is imperative that wealthy nations assist them in developing their research, biosecurity, and surveillance capacities, and not use the dual-use issue as an inappropriately applied obstacle to scientists' work visas and immigration. Although the combined impact of these recommendations will not entirely eliminate DURC-related biological threats, the resulting raised levels of governments' awareness, readiness, and response capacities would both vastly improve the prevention of disease and outbreaks, and minimize the health, economic, political, and environmental damage caused by a deliberate or accidental release of synthesized or GOF-altered organisms.

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