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GUEST EDITORIAL

The "Nuclearization" of Biology Is a Threat to Health and Security

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Every technology, from fire to gunpowder to aviation, has been used by humans largely for good but also for harm. But the capabilities of an individual or group to do great harm have increased markedly in the past 50 years. In the mid-20th century, we developed nuclear weapons, but these have remained in the hands of nation-states because it would be extraordinarily difficult for even a technically competent group of individuals to gain access to the singular ingredients—highly enriched uranium or reprocessed plutonium—and the technology to develop a nuclear weapon and thus cause incalculable harm and mass death. To date we have controlled the proliferation of nuclear weapons by safeguarding the rare elements needed to produce them and by carefully screening scientists and technicians for their physical and mental health. Today, only a few nation-states have the bomb, and there have been zero accidental or terrorist detonations.

More recently, our understanding of biology and the means to utilize it have improved greatly. Indeed, we've seen a revolution in recombinant DNA technology, synthetic genomics, nanotechnology, and *de novo* synthesis of microbes, among many examples. These powerful tools and information are now found in secondary schools around the

globe and in homes of do-it-yourself genetic engineers. Proliferation of the biotechnologies is essentially complete.

In 1996, one "outlier biologist" attempted to acquire a common, but potentially lethal, pathogenic microbe from the American Type Culture Collection. In response, alarmed legislators called for an official list of "dangerous pathogens" and the registration of laboratories that exchanged those pathogens. As a result, in 1997, the "nuclear model" was applied to biology for the first time. Years later, a series of "anthrax letters" killed 5 individuals, frightened tens of thousands of people, and precipitated a significant degree of government and economic disorder, prompting scientists to increasingly engage in discussions of "dual-use biology"—that is, biology that could be used for malevolent as well as benevolent purposes. Then, on July 28, 2008, a respected senior scientist at Ft. Detrick, Maryland, committed suicide just before the Department of Justice was to seek an indictment charging him with crimes having to do with the anthrax letters.

Now, the U.S. government is once again looking to the nuclear model to further regulate biology. It is worth pausing to reflect whether this is a wise strategy, given the dichotomy between the nuclear and biological threats. The

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first involves rare materials and costly, complicated science and is practically restricted to nation-states; the second involves agents that can be inexpensively and readily obtained and science not restricted to nation-states but available to rogue individuals and organizations. These fundamental differences between biological and nuclear weapons strongly suggest that nuclear counterproliferation and prevention strategies are not applicable to biology. We need to think of alternative security models.

National committees are pondering the solution to the "insider threat," described as our greatest menace in the 2008 report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. As the revolution in biology—and capabilities to do good or harm with its tools and knowledge—roars around the globe, our legislators seemingly are viewing with increasing suspicion all scientists who work with a very short and specific list of "dangerous" microbes.

Despite this assault, much of the scientific community is on the sidelines. Either this controversy hasn't yet had an impact on their research on other infectious disease—causing agents, synthetic genomics, nanotechnology, or studies of the human immune system, or they have chosen lesscontroversial areas of research. But the regulation of responsible scientists and legitimate technologies and microbes with the goal of eliminating a threat that may involve 1 individual among 10 million humans is tricky business. We cannot really know if we've over-regulated to the detriment of science in the U.S. because it is impossible to estimate the cost of research that is not done. However, by over-regulating life sciences research, the U.S. paradoxically could make itself more vulnerable. We must carefully consider the real risks of legitimate science and the real costs of regulation. Otherwise, there is no doubt that the sustained valuable discoveries of our life sciences enterprise will suffer.

Life sciences research offers all of us better health and security. Biological science provides our primary, continuing defense against diseases, natural or man-made, with knowledge that can be translated into effective countermeasures such as vaccines and new therapies. Any regulation that unnecessarily hinders this research is a real and unnecessary threat to our health, our economy, and our national security. It thus is critical that the entire bioscience community join the discussion with legislators and the public now—before we start down a regulatory slippery slope that could harm science in the U.S. forever.