

## Bioterrorism: Lessons Learned Since the Anthrax Mailings

**ABSTRACT** In the fall of 2001, *Bacillus anthracis* spores were spread through letters mailed in the United States. Twenty-two people are known to have been infected, and five of these individuals died. Together with the September 11 attacks, this resulted in a reevaluation of the risks and benefits of life science research with the potential for misuse. In this editorial, we review some of the results of these discussions and their implications for the future.

It is the 10th anniversary of the mailing of the anthrax spores, a tragic event that resulted in five deaths, seventeen other known infections, and untoward fear among the population. The cleanup is estimated to have cost \$1 billion. What have we learned and accomplished in the interim?

Of course, one cannot consider the anthrax mailings in a vacuum, coming on the heels of the September 11 attacks on the World Trade Center, the Pentagon, and United Airlines flight 93. The reaction from Congress was swift: the United States PATRIOT Act was signed into law in October 2001, and the Public Health Security and Bioterrorism Preparedness Response Act followed in June 2002. Together, these pieces of legislation put restrictions and limits on who could access and possess select agents, those pathogens deemed by the CDC and USDA to be the most dangerous. A considerable amount of funding was also earmarked for research on these pathogens.

A series of policy discussions have also ensued. The government solicited studies from the national academies on various topics relating to science and security, other federal advisory panels were formed, and the government itself has addressed bioterrorism at various levels. Numerous nongovernmental organizations throughout the world, including the American Association for the Advancement of Science (AAAS), have also engaged scientists, security experts, ethicists, and others in an ongoing, fruitful discussion. While the specific charge to each of these groups differed, they all have addressed a common question: how do we ensure a vibrant research enterprise without compromising national security? This question is of central importance given that the 21st century promises to be the biological century, which will likely spawn many new life science-based technologies and industries that will improve our lives.

The answer to this question is not straightforward, mainly because of the nature of life science research. The risks that present themselves as a result of the acquisition of new knowledge are difficult to predict or quantify, while the potential benefits are more concrete. In addition, the results of experiments are sometimes unpredictable. Therefore, determining whether certain types of research should be prohibited or regulated is difficult. The consensus reached by both the scientific and national security communities is that research should proceed, with all involved being vigilant for the potential of misuse. The National Science Advisory Board for Biosecurity, which has been charged since 2005 with providing recommendations to the U.S. government on the oversight and conduct of “dual use” research, has developed a series of thoughtful reports that suggest a balanced approach to the topic (see <http://www.biosecurityboard.gov>). Perhaps the most important contribution of this body was to acknowledge that most if not all biological research had “dual use” capabilities while creating a special category known as “dual use research of concern” (DURC) and the tools to identify it. This was important

because it had the effect of walling off the small part of the scientific effort that was most relevant to the threat of bioterrorism and thus leaving the vast majority of biological research undisturbed and unregulated.

Another valid concern is whether certain individuals should not be allowed to access select agents. While some groups have now been excluded categorically by the above-mentioned statutes, vigorous discussions concerning personnel reliability in a broader sense continue. Attention to an “insider threat” was amplified by the identification of Bruce Ivins, a scientist working in a U.S. government laboratory, as the possible perpetrator of the anthrax attacks. The emerging consensus is that ongoing attention to lab workers’ trustworthiness, behavior, and attitude is the best means to reduce the risk that someone might deliberately cause harm.

What has the overall effect of these activities been on the life science research enterprise? We would argue that it has been a mixed bag. The infusion of extra research dollars has been welcome, especially at a time when federal funding of biology research overall has suffered. Increased attention to the possible risk of misuse may also make us safer. However, a small but significant number of investigators have chosen to discontinue working in the field due to the added regulatory burden. It is difficult to assess how many others are not entering into this area, but anecdotal evidence suggests this is occurring more than one would like. Perhaps of greater concern is that important research, such as the development of new vaccines against anthrax, has been slowed by the need to work within the new regulatory and statutory framework. Compliance with select agent rules has significantly increased the cost of research on certain pathogens (1). The enactment of the select agent rules led to the destruction of several microbial collections (2) and is almost certainly interfering with the establishment of new collections or saving of new clinical isolates, given the enormous work involved in having such isolates transferred to secure facilities. Furthermore, the focus on containing microbial threats by generating lists of organisms for special consideration may have created a false sense of security while greatly increasing the regulatory burden (3).

We are very fortunate that 10 years have passed with no additional bioterrorism events. This is a testament to the effort of scientists behaving responsibly and working together with the national security community to minimize the risks. While ideally,

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one would like to reduce the risk to zero, living in the real world, we know that zero risk would mean little progress and that an impaired research enterprise will leave us more vulnerable. Our nation was built by, and has thrived on the efforts of, risk takers. The current oversight system for life science research is functional and robust, ensuring that the pace to discovery is limited only by intellectual and fiscal resources.

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