



BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM (2004)

The great achievements of molecular biology and genetics over the past 50 years have produced advances in agriculture and industrial processes and have revolutionized the practice of medicine. The very technologies that fueled these benefits to society, however, pose a potential risk as well—the possibility that these technologies could be used to create the next generation of biological weapons. Biotechnology represents a “dual use” dilemma in which the same

technologies that can be used to better society can also be misused for bioterrorism with devastating results.

Policymakers and the scientific community need to respond to this threat by developing a system that permits fundamental research to proceed, while at the same time reducing the risks that research results might be misused. The plan outlined here includes a process for reviewing scientific research activities through all the phases from proposal to publication to ensure that they receive the necessary oversight. This process relies heavily on a mix of voluntary self-governance by the scientific community and expansion of an existing regulatory process that grew out of the scientific community’s earlier response to the risks of gene-splicing research.

Ensure that Research is Not Limited

The USA PATRIOT Act of 2001 and the Bioterrorism Preparedness and Response Act of 2002 established the regulatory basis for protecting biological materials from misuse. Implementing the current legislation should not be overly restrictive given the critical role that the development of effective vaccines, diagnostics, therapeutics, and detection systems, along with a responsive public health system, will play in providing protection against bioterrorism and other serious health threats. Otherwise, research on dangerous pathogens by legitimate laboratories and investigators may be limited unintentionally. Although the United States needs to take action domestically, to be effective, a harmonized, international system for oversight of dangerous pathogens and toxins is needed.

Educate the Scientific Community

National and international professional societies and related organizations should create programs to educate scientists about the nature of the dual use dilemma in biotechnology and their responsibilities to mitigate its risks. Professional societies in the life sciences should organize meetings and symposia, in the United States and abroad, to provide both knowledge and opportunities for discussion. Industry groups and associations of higher education and research should also educate their members about the risks and implications for research practices.

Enhance the Review System for Experiments

The Department of Health and Human Services (DHHS) should augment the current system for reviewing experiments involving recombinant DNA conducted by the National Institutes of Health. This involves developing a review system for seven classes of experiments involving microbial agents that raise concerns about their potential for misuse. The review system must include criteria for deciding which experiments will be subject to review and the process by which the review will take place.

Rely on Self-governance for Review of Publications

Review of publications for their potential national security risks should be done by the scientists and scientific journals themselves, as a group of editors from major journals undertook in 2003. It is essential that journal staff and the national security community create a system that is considered responsive to the risks but also credible with the research community.

With regard to classification, the principle set out by the Reagan Administration in 1985 in National Security Decision Directive 189—that the results of fundamental research should be unrestricted to the maximum extent possible and that classification should be the mechanism for what control might be required—remains valid and should continue to be the basis for U.S. policy. Self-governance by the scientific community through appropriate reviews by journals and other publication outlets should not be considered as endorsing the creation of “sensitive but unclassified” information in the life sciences.

Create a National Science Advisory Board for Biodefense

DHHS should create a National Science Advisory Board for Biodefense (NSABB) to provide advice, guidance, and leadership for the proposed system of review and oversight. The NSABB would serve a number of important functions for both the scientific community and the government, including:

- Continue dialogue between scientific and national security communities.
- Provide case-specific advice on oversight of research.
- Communicate life sciences research information relevant for national security and biodefense purposes.
- Help professional societies develop educational programs.
- Assist life science publications.
- Provide a way for journal editors to exchange information.
- Advise the government on how the life sciences can contribute to alleviating the risks of bioterrorism and biological weapons through new research in areas such as vaccine, antiviral, and antibiotic development, new detection devices and technologies, and preventive public health measures.

Improve Communication between Security, Law Enforcement, and Life Science Organizations

The national security and law enforcement communities should improve communication with the life sciences community about how to mitigate the risks of bioterrorism. It is imperative that the United States conduct its legitimate defensive activities in an open and transparent manner to allow biomedical scientists to contribute to developing measures that will minimize the impact of bioterrorism.

The intelligence and law enforcement agencies rely on academic scientists for their expertise about the nature of current agents and the potential for new ones, and for the best advice on limiting the spread of new technologies that would make countermeasures more difficult. In addition, the national security community needs to establish advisory boards of scientists and clinicians with expertise in viral diseases, bacterial pathogens, biotechnology, immunology, toxins, molecular biology, and public health. These advisory boards could help members of the intelligence and law enforcement communities stay on top of relevant areas of science and technology and provide a trusted set of advisors to answer technical questions.

Review Physical Containment and Personnel Issues

Issues related to regulation of physical containment and trained personnel should be reviewed and evaluated because of their important impact on how research is conducted. Physical containment, which involves safeguarding existing agents, is a priority being addressed through recently passed legislation, but the lists and process need consistent review and updating. Some current efforts to identify or control knowledgeable personnel within the United States are impractical, and surveillance of such personnel would not offer much security.

Coordinate International Oversight

Any attempt to reduce the risks associated with biotechnology must be international in scope because the technologies that could be misused are being developed around the world. Additionally, international consensus and consistent guidelines for overseeing research in advanced biotechnology are necessary in order to prevent limitations on certain types of research in the United States that would impede the progress of biomedical research and undermine national interests. Therefore, the international policymaking and scientific communities should create an International Forum on Biosecurity to develop and promote coordinated national, regional, and international measures that will provide a counterpart to the system recommended for the United States.

Conclusion

Policies to counter biological threats should not be so broad that they prevent the life sciences community from continuing its role of contributing to the betterment of life and improving defenses against biological threats. Caution must be taken when adopting policies to respond to this threat so results will be achieved without creating unintended consequences. On the other hand, the potential threat from the misuse of biological research is a challenge to which policymakers and the scientific community must respond. Only a system of international guidelines and review will ultimately minimize the potential for the misuse of biotechnology.

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Copies of *Biotechnology in an Age of Terrorism* are available from the National Academy Press; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP online at www.nap.edu. For questions concerning this project, contact staff at (202) 334-2816 or visit the Policy and Global Affairs website at www.nationalacademies.org/pga.

^a Until August 2003.

^b Until November 2002.