Chapter 8: Bringing Biosecurity-related Concepts into the Curriculum: A US View

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The decades flanking the September/October 2001 terrorist incidents in the US (1990–2010) have seen a dramatic increase in concern with and attention to biological weapons (BW). The discovery of an extensive offensive BW programme in the former Soviet Union, the unsuccessful attempts of Aum Shinrikyo and US domestic terrorists to acquire, produce and disseminate 'weaponised' biological agents, and the anthrax attacks through the US Postal Service are among the events that have contributed to increased awareness of a possible biological threat.

While assessments of the actual threat remain controversial, the perceived threat already has led to extensive changes in the conduct and regulation of scientific activity in the US. In the past decade, concern with biological weapons and biodefence has been accompanied by massive increases in funding directed towards civilian biodefence: over $50 billion between 2001 and 2009.[1]

An enormous amount of federal effort and capacity is now directed towards select-agent research, in particular, and infectious-disease research in general.

Accompanying this push in infectious-disease research are requirements for compliance with increased regulatory activity at federal, state and institutional levels.[2] The changes include enhanced personnel and site-security oversight, consideration of delaying publication of relevant results, and greater regulation and management of experimental research. Thus far, systems of control have focused largely on laboratory biosafety and biosecurity, by regulating manipulation of and access to highly infectious organisms. The impetus for this has come largely from federal agencies.

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1 Franco, C. 2009, 'Billions for biodefense: federal agency biodefense funding, FY2009–FY2010', *Biosecurity and Bioterrorism*, vol. 7, September, pp. 291–309.

2 Jaax, J. 2005, 'Administrative issues related to infectious-disease research in the age of bioterrorism', *Institute of Laboratory Animal Resources Journa*l, vol. 46, pp. 8–14.

Also, a series of recent experiments in infectious-disease research (discussed in other chapters in this volume) have brought the concept of 'dual use' to the fore. For decades, the term 'dual use' was applied to the civilian/military duality. This concept has continued to evolve. Today the concern is that most technologies developed for legitimate purposes are intrinsically capable of being exploited for nefarious ones. It is not difficult to appreciate this potential in contemporary life sciences. There have been a number of pivotal technical advances in biomedical research over the past two decades. For example, the introduction of polymerase chain reaction in 1983 permitted the measurement of gene expression with previously unimaginable precision; the application has continued to develop novel applications. Current imaging techniques allow precise mapping of metabolic and signalling pathways, in real time and in whole animals, including humans. Nanotechnology and microfluidics have created more-effective delivery methods of drugs, hormones, and bioregulators. Increased information relating to physiology, behaviour and disease paves the way to new methods of controlling biological responses in medicine and improving human life. Yet, it can be argued that each of these advances is accompanied by the potential for malfeasance. In relation to dual-use concerns, the Fink and Lemon/Relman Reports[3] argued that the scientific community must increase its involvement in the development of policy. The creation of the National Security and Biosafety Board (NSABB) has been a useful exercise in focusing the attention of leaders in academic and commercial research on this topic.

Interest in dual use continues to grow. In 2009, the American Association for the Advancement of Science (AAAS) and the National Academies of Science (NAS) jointly published a report titled *A Survey of Attitudes and Actions on Dual-use Research in the Life Sciences*.[4] The results of the study suggested that the majority of life-sciences researchers in the US supported the concept of oversight models that rely on self-governance and responsible conduct, but that clarification of a number of issues is required. This included matters such as defining the scope of research and experiments of concern, establishing appropriate training mechanisms, and identifying ways that scientists can contribute to the prevention of misuse of scientific knowledge. These same issues were revisited in a series of recent workshops held by the AAAS to examine existing programmes in dual-use education and in biodefence policy training.[5] From these studies, it became clear that most academic institutions

3 National Research Council 2004, *Biotechnology research in an age of terrorism*, Washington, DC: National Academies Press; Institute of Medicine and National Research Council 2006, *Globalization, biosecurity and the future of the life sciences*, Washington, DC: NRC.

4 National Research Council/American Association for the Advancement of Science 2009, *A Survey of Attitudes and Actions on Dual Use Research in the Life Sciences: A Collaborative Effort of the National Research Council and the American Association for the Advancement of Science*, Washington, DC: NRC/AAAS.

5 American Association for the Advancement of Science 2009, *Building the Biodefense Policy Workforce*, Washington, DC: AAAS; American Association for the Advancement of Science 2008, *Professional and*

provide few resources for or demonstrate little interest in dual-use education. Further, educational materials are lacking, as are methods and analysis of their efficacy. The National Science Advisory Board for Biosecurity (NSABB) released its *Strategic Plan for Outreach and Education on Dual-use Research Issues* in 2008.[6] A joint letter[7] to the NSABB from the AAAS, the American Association of Medical Colleges (AAMC), the Association of American Universities (AAU), the Council on Government Relations (COGR), the Federation of American Societies for Experimental Biology (FASEB) and the Association of Public and Land-grant Universities (NASILGC) outlines these groups' apprehension with the mechanism of review, the determination of whether specific dual-use research would be categorised as being 'of concern', and the lack of clarity concerning liability issues that might lead to a dampening of scientific enterprise.

Dando[8] and others have called for the creation of a 'culture of responsibility'. This chapter will discuss approaches to this challenge in the current US academic environment. The idea of instilling a culture of social responsibility among scientists with respect to security issues is underpinned by the question of disclosure mechanisms, anonymity, and whistleblower protection. These are not novel topics, and are included in current standard biomedical-ethics curricula. However, disclosure of unusual or inappropriate activity takes on additional significance when the behaviour might be tied to national security.

Thus, in the last decade the US has witnessed the introduction of a number of new concepts to the life sciences. The process of doing science has been permeated by security and safety regulations that in turn have stimulated interest in the ethical and even moral issues related to the misuse of life-sciences research. Studies are accumulating to evaluate whether practising scientists are aware of these ideas, either by exposure or on their own, and which educational institutions have introduced these concepts into ethical-training programmes. Other chapters in this volume detail these studies in different parts of the world. Here, we discuss the challenge of introducing biosecurity

Graduate-Level Programs on Dual Use Research and Biosecurity for Scientists Working in the Biological Sciences, Washington, DC: NRC/AAAS.

6 NSABB 2007, *Proposed framework for the oversight of dual-use life sciences research: Strategies for minimising the potential misuse of research information*, Bethesda, MD: NSABB; NSABB 2008, Strategic plan for outreach and education on dual-use research issues, Bethesda, MD: NSABB.

7 Joint letter, 18 July 2008, to NSABB from the American Association for the Advancement of Science (AAAS), The American Association of Medical Colleges (AAMC), The Association of American Universities (AAU), The Council of Governmental Relations (COGR), The Federation of American Societies for Experimental Biology (FASEB) and The National Association of State Universities and Land-Grant Colleges (NASULGC, now the Association of Public and Land-grant Universities (APLU)), available: www.aau.edu/WorkArea/DownloadAsset.aspx?id=9740 [viewed 15 Mar 2010].

8 Atlas, R. and Dando, M. 2006, 'The dual-use dilemma for the life sciences: Perspectives, conundrums, and global solutions', *Biosecurity and Bioterrorism*, vol. 4, September, pp. 1–11; Revill, J. and Dando, M. 2008, 'Life scientists and the need for a culture of responsibility: After education…what?', *Science and Public Policy*, vol. 35, February, pp. 29–36.

and dual-use matters within the context of existing programmatic frameworks in a typical US academic biomedical-research institution. Over the past 15 years we have developed a number of avenues for introducing the concept of dual-use research to the university community at our institution. The first is through the federally mandated 'Responsible Conduct of Research' education of National Institute of Health (NIH)-sponsored trainees. The second route is via the Institutional Biosafety Committee, originally mandated by the NIH in the 1970s to review experiments involving recombinant DNA and since expanded to include infectious agents. The third avenue is the laboratory safety training mandated by the Occupational Safety and Health Association (OSHA) for all laboratory workers. The fourth route is through a robust biodefence 'certificate' academic curriculum, open to all students at the university regardless of programme (PhD, MS, MD, nursing, and so on). We propose a fifth approach using an institutionally based 'train-the-trainer' system of intercalating dual-use awareness into individual academic departments through periodic seminars and discussion groups. We discuss the strengths and limitations of each of these approaches in terms of topics, efficacy and audience.

Route One: Responsible Conduct of Research

An examination of the history of incorporation of ethical issues into the US curriculum will enrich this exploration of mechanisms for introducing biosecurity and dual use into the academic biomedical curriculum. Formalised ethics training was introduced just over two decades ago in the US federally supported scientific enterprise. The impetus was a series of fraud/misconduct cases at four research institutions in 1980 that were widely publicised, leading to widespread calls for a concerted effort to include ethics training within the medical school curriculum, originating from both lay and medical groups. The first congressional hearing uncovering additional cases took place that same year, in the Investigations and Oversight Subcommittee of the House Science and Technology Committee.

In 1985, Congress passed the Health Research Extension Act, which required that Health and Human Services (HHS) awardee institutions establish 'an administrative process to review reports of scientific fraud' and 'report to the Secretary any investigation of alleged scientific fraud which appears substantial'. The Final Rule, *Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science*, was published in the Federal Register in 1989 and codified as 42 CFR Part 50, Subpart A. The Office of Research Integrity (ORI) was established in its current iteration — that is, independent of the funding agencies — in 1992. The Commission on Research Integrity published a report titled *Integrity and Misconduct in Research*

in November 1995.[9] It contained 33 recommendations, among which was the requirement of funded institutions to establish educational programmes on the responsible conduct of research (RCR).

The term 'misconduct' has evolved from its original definition of 'fraud, fabrication and plagiarism' to include 'other serious deviations from commonly accepted practices'.[10] In 1999, policy was developed requiring all extramural research institutions to provide training in RCR to all staff who have 'direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training, support by Public Health System (PHS) funds or who otherwise work on PHS-supported research projects even if the individual did not receive PHS support'. Eight topics are required in addition to misconduct (fraud, fabrication and plagiarism): data acquisition, sharing and management; conflict of interest; animal protection; human-subject protection; publication and authorship; mentor–trainee responsibilities; peer review; and collaborative science. Scientific research is conducted in a constantly changing environment and RCR training has undergone gradual shifts in focus. Regulatory changes, electronic publishing, and data sharing have compelled adjustments or additions to the topics. The policy was suspended in February 2001 pending review and, interestingly, a ruling on whether the document should have been issued as a ruling remains suspended. Whistleblower protection was also reviewed, although the final rule has been pending since January 2001. However, the Whistleblower Protection Act of 1989 protects federal employees, individual institutions and corporations have their own protection policies implemented at state and institutional levels.

It would appear from this brief review of the history of RCR training and guidance in the NIH that this programme would be an excellent framework for the introduction of dual-use concepts to life scientists. Indeed, the Office of Intramural Research at the NIH has already explored new case studies and scenarios ('Science and Social Responsibility — Dual Use Research 2009' [11]) for inclusion in RCR training within the NIH's own intramural programme, which requires annual ethics training for all regular NIH employees — not only trainees.

Whether the RCR mechanism will provide adequate training of dual-use issues remains an important question. Recent studies of standard RCR training methods

9 Rhoades, L. J. 2004, *New Institutional Research Misconduct Activity: 1992–2001. Office of Research Integrity*, available: ori.dhhs.gov/education/products/rcr_misconduct.shtml [viewed 15 Mar 2010].

10 American Association for the Advancement of Science and the US Office of Research Integrity 2000, *The Role and Activities of Scientific Societies in Promoting Research Integrity. A Report of a Conference*, available: http://www.aaas.org/spp/sfrl/projects/report.pdf.

11 NIH Committee on the Conduct of Science 2009, *Science and Social Responsibility — Dual Use Research 2009,* available: www1.od.nih.gov/oir/sourcebook/ResEthicsCases/2009cases.pdf [viewed 15 Mar 2010].

have pointed to wide variation in both approaches and efficacy. Antes *et al*.,[12] who concluded that effectiveness was 'modest', carried out a meta-analysis of ethics instruction in the sciences. They noted that success was tied to course structure (case-based illustration and discussion was more effective than lecture) and context (instruction separated from standard curricula rather than included within existing courses). Others[13] argue that all trainees in our universities should be expected to understand basic principles of academic integrity and, further, to gain expertise in ethical issues in their individual fields. The study of Heitman *et al*.[14] observed a disheartening lack of knowledge among trainees upon entering graduate school, irrespective of previous research experience, ethics training, or country of origin; the authors suggest RCR training might be modified to adjust to gaps in knowledge and experience. Finally, a troublesome study by Anderson *et al*. examined early- and mid-career NIH-funded scientists who had received NIH-mandated RCR training.[15] Not only had many of the respondents little to no recollection of that teaching, but the study also found under some conditions a positive correlation between research-integrity training and behaviour that was inconsistent with that teaching. Critics of the entire RCR training enterprise claim that scientists as educated adults already have a moral framework within which the core concepts of RCR are adequately contained. These and many other studies suggest that our academic institutions should consider alternative educational methods for effective ethics training; and dual-use awareness should be included in the discussions.

In a December 2009 editorial titled *Bringing a 'Culture of Responsibility' to Life Scientists*,[16] Malcolm Dando pointed out that many researchers consider RCR training adequate for developing a culture of responsibility. Dando further observed that neither the ORI nor professional societies with similar agendas, such as the NAS or the Royal Society, had yet incorporated dual-use issues in any formal way. Washington's recent 'National Strategy for Countering Biological Threats'[17] contains as its second objective the 'reinforce[ment of] norms of safe

12 Antes, A., Wang, X., Mumford, M. D., Brown, R. P., Connelly, S. and Devenport, L. D. 2010, 'Evaluating the effects that existing instruction on responsible conduct of research has on ethical decision making', *Academic Medicine*, vol. 85, March, pp. 519–26.

13 Bulger, R. E. and Heitman, E. 2007, 'Expanding responsible conduct of research instruction across the university', *Academic Medicin*e, vol. 82, September, pp. 876–8.

14 Heitman, E., Olsen, C. H., Anedtidou, L. and Bulger, R. E. 2007, 'New graduate students' baseline knowledge of the responsible conduct of research', *Academic Medicin*e, vol. 82, September, pp. 838–45.

15 Anderson, M. S., Horn, A., Risbey, K. R., Ronning, E. A., De Vries, R. and Martinson, B. C. 2007, 'What do mentoring and training in the responsible conduct of research have to do with scientists' misbehavior? Findings from a national survey of NIH-funded scientists', *Academic Medicin*e, vol. 82, September, pp. 853–60.

16 Dando, M. 2009, 'Bringing a ''culture of responsibility'' to life scientists', *Bulletin of the Atomic Scientists*, 18 December, available: http://www.thebulletin.org/web-edition/columnists/malcolm-dando/bringing-culture-of-responsibility-to-life-scientists [viewed 15 March 2010].

17 National Security Council 2009, *National strategy for countering biological threats*, available: http://www.whitehouse.gov/the-press-office/president-obama-releases-national-strategy-countering-biological-threats [viewed 15 March 2010.

and responsible conduct' by developing appropriate training programmes and materials. Dando mused whether these strategies will be implemented in time for the Seventh Review Conference of the BWTC in 2011.

Integration into Ethics and Responsibility Training: A Case Study

What follows is a description of the gradual incorporation of biosecurity and dual-use issues into the RCR curriculum of the University of Medicine and Dentistry of New Jersey (UMDNJ) that began in 1994 at the Newark branch of the Graduate School of Biomedical Sciences (GSBS). The GSBS in Newark presents its RCR course for PhD students at the end of their second year, just as they finish the didactic segment of their training and enter the laboratory full time. The course is team-taught and the lecturers represent various departments and regulatory cores of the institution. The teaching style is a mix of lecture and interactive case-study discussion. In 1994, a single lecture, titled 'Biological and Toxin Weapons', was introduced into this course and focused on the history of biological and toxin weapons use, the nature of the agents and the difficulties in working with them, the past offensive programmes of the US, UK, Japan and USSR, weapons-testing programmes, and the history and development of the BTWC. Discussion topics included the verification protocol that was under development and the responsibility of scientists to recognise and support the BTWC. Students were urged to think about problems in detection of production or weaponisation methodology and learned about the pledge, circulated by the US Council for Responsible Genetics in 1989, that scientists not participate knowingly 'in research and teaching that will further the development of chemical and biological agents'. Although dual-use issues were not yet a primary focal point of the BTWC Review Conferences, codes and the dual-use dilemma were already part of the discussion in many scientific circles.

There were two subsequent changes in the focus of UMDNJ's lecture as the years went by. One was in 1999 when the institution established a biodefence-research programme, forming the UMDNJ Center for BioDefense, accompanied by construction of a new Biosafety Level Three laboratory for the study of infectious respiratory micro-organisms, including select agents. The RCR lecture in bioweapons expanded at this point to include the topics of biosafety and biosecurity, natural versus man-made outbreaks of disease, and so on. The Center for BioDefense had a strong Emergency Response training component that further expanded the scope of the lecture. The BTWC and the responsibility of scientists in maintaining awareness of a possible biological arms race, including the UN inspection teams, remained the cornerstone of the lecture. The second major change in structure of the RCR lecture was in Spring 2002, four months after the anthrax attacks. At this juncture, the lecture began to include yearly

updates in the anthrax mailing case, biological terrorism, and so on. In fact, a group of graduate students approached the Center for BioDefense asking for full-length courses in both basic science and policy. In response to this request, a certificate programme in biodefence was developed (discussed below).

UMDNJ is a large institution, with three branches of the graduate programme in different parts of the state of New Jersey. Inquiries directed at the Center for BioDefense from other segments of the GSBS suggested that students across the university would benefit from knowledge of such things as select-agent research, and biosafety and biosecurity regulations. Therefore, approximately 75 students per year are taken through a two-hour lecture and interactive discussion of the history of biological weapons, arms control, codes of conduct and the dual-use dilemma.

Nevertheless, using the RCR to introduce biosecurity and dual use-issues has a number of limitations. For example, only graduate students take this course. How would Principal Investigators (PIs) be included in the programme? The NIH and a very small number of universities have included PIs in their training programmes, but this is rare.21 The RCR requirement for trainees was initiated in 1995, and assuming these first students left college soon after, they should now be at assistant- or associate-professor level, or the equivalent in industrial settings. These researchers have been surveyed regarding the effectiveness of RCR training, as discussed above.[18]

There are other groups of scientists who play significant roles in the scientific enterprise who are often not included in RCR training. The first comprises those in post-doctoral training: recently, the National Postdoctoral Association has introduced materials for RCR training on its website[19] and the NIH now requires RCR training for recipients of its 'K-series' of awards, for which post-docs and junior faculty are eligible. The second group are the research technical staff: it is possible that these groups can be reached through laboratory safety training, described below.

18 Anderson *et al*. 2007, op. cit.; Antes *et al*. 2010, op. cit.

19 National Postdoctoral Association 2009, *Tailoring RCR programs for postdocs*, available: http://www.nationalpostdoc.org/publications/rcr/112-pda-toolkit-tailor-to-postdocs [viewed 15 March 2010].

Route Two: The Institutional Biosafety Committee

A second introductory route of biosecurity and dual use into the curriculum is through the Institutional Biosafety Committee (IBC). IBCs were established in the 1970s in response to alarm and concern in the scientific community over the potential dangers of the then novel recombinant DNA technology. The NIH *Guidelines for Research Involving Recombinant DNA Molecules*[20] have been continually updated and are now under the charge of the Office of Biotechnology Activities. The Recombinant DNA Advisory Committee (RAC) members are responsible for oversight of these activities by interpreting the NIH Guidelines (latest version, September 2009). Appendix G is the section that deals with physical containment and biosafety. In June 2009, a 'Tool for the Self-Assessment of the Institutional Biosafety Committee and Programme of Oversight of Recombinant DNA Research'[21] was released, which allows individual IBCs to evaluate their effectiveness and compliance with federal regulations. The IBC reviews and approves all research involving 'non-exempt' recombinant DNA, pathogenic micro-organisms and/or potentially infectious materials requiring work at Biological Safety Level 2 (BSL-2) or above. Research protocols are prepared by principal investigators and submitted for appraisal before the work is begun: the major review focus is the safety of workers carrying out the experiments and the community, both within and outside the institution.

As the purview of the IBCs has expanded from recombinant DNA to include pathogen research, these committees have been identified as a control point for oversight of research with dual-use potential. The Fink Report advocated expanding the responsibilities of IBCs to include biosecurity and dual-use concerns.[22] However, this suggestion has been met with criticism: in the NAS report *Science and Security is a Post-9/11 World*,[23] David Relman is quoted as saying, 'Today's IBC's can't do biosecurity because the members have not been adequately informed about how you think [about] biosecurity, how you think about the potential misuse of science'.[24] While Relman's point is well made, the

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20 Office of Biotechnology Activities 2002, *NIH Guidelines for Research Involving Recombinant DNA Molecules*, available: oba.od.nih.gov/rdna/nih_guidelines_oba.html [viewed 15 March 2010].

21 Office of Biotechnology Activity 2009, *Tool for the Self-Assessment of the Institutional Biosafety Committee and Program of Oversight of Recombinant DNA Research*, available: oba.od.nih.gov/rdna_ibc/ibc.html [viewed 15 March 2010].

22 National Research Council 2004, *Biotechnology research in an age of terrorism*, Washington, DC: National Academies Press.

23 National Research Council 2007, *Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities*, Washington, DC: National Academies Press.

24 Relman, D. 2006, Remarks made at the Committee on a New Government–University Partnership for Science and Security Western Regional Meeting at Stanford University, 27 September, available: www7.

past few years have seen a wealth of information and scholarly articles addressing these issues. Several training modules have been developed for online use and IBC members might be required to undergo these training modules. Much of this dual-use material was analysed at a series of workshops held by AAAS[25] and reviewed by the NSABB[26]. For example, online modules are sponsored by the following organisations:

- Duke University (SERCEB) at: www.sercebtraining.duhs.duke.edu/
- Federation of American Sciences at: www.fas.org/biosecurity/education/dualuse/index.html
- NIH Office of Research Integrity at: www1.od.nih.gov/oir/sourcebook/ResEthicsCases/2009cases.pdf
- The Center for Arms Control and Nonproliferation at: www.politicsandthelifesciences.org/Biosecurity_course_folder/base.html.

Other contributors to this volume have also outlined additional resources.

Integration into the Institutional Biosafety Committees: A Case Study

The IBC at UMDNJ in Newark has taken specific steps to begin introducing dual use into its agenda. Members of the IBC have all taken the online dual-use-awareness modules developed by Duke University (SERCEB) and they now evaluate submitted protocols for dual-use potential in their discussions. The Newark IBC is currently considering appropriate language to incorporate questions regarding dual use into the IBC protocol application itself, thereby involving the PI directly. The Department of Environmental and Occupational Health and Safety Services has published the first of a series of articles in its monthly newsletter on dual-use experimentation. This newsletter is widely distributed across the entire campus. The goal is to introduce these ideas across the university community, reaching PIs, trainees and staff in all fields, regardless of whether they work with recombinant DNA or pathogenic organisms.

As with integrating dual-use education into the RCR component of life-sciences instruction, there are drawbacks to the approach of solely relying on the IBC as a vehicle for dual-use education. In addition to the possible lack of expertise and experience discussed above, not all research with potential dual-use application is captured by the IBC as it is currently configured. It focuses on experiments using recombinant DNA and/or highly infectious agents. Research

nationalacademies.org/stl/202006.pdf [viewed 15 March 2010].

25 American Association for the Advancement of Science 2009, *Building the Biodefense Policy Workforce*, Washington, DC: AAAS.

26 NSABB 2008, op. cit.

not involving these activities will not be captured. Most, but not all, life-sciences research uses molecular biology and cloning, but protocols from fields using technologies identified as dual use in nature, such as neural imaging or nanotechnology — projects that do not use rDNA — will not be reviewed. Other regulatory committees in biomedical research are those that oversee laboratory-animal welfare and human-subjects protection: these institutional committees might be engaged to evaluate proposals for dual-use potential.

These limitations argue for a broader approach, one that includes all kinds of research and targets executives, administrators, PIs, technical staff and trainees. Laboratory Safety Training is a requirement for all laboratory workers, and provides a third level of introduction to dual-use issues.

Route Three: Laboratory Safety Training

A third route of entry is through the Laboratory Safety Training required for all laboratory workers: PIs, post-doctoral fellows, graduate students, technicians and other staff. The OSHA has identified within its array of standards for general industry those with specific application to laboratories.[27] Topics include chemical safety/'right-to-know',[28] hazardous-waste and regulated medical-waste handling, fire safety, personal protective equipment, and emergency procedures. The training at UMDNJ lasts two hours and is given at the time of hire, followed by a short refresher course every other year thereafter. Laboratory biosafety and biosecurity are topics usually covered and dual use might be incorporated. However, we have found the brevity of such an introduction to a complex issue like dual-use research is inadequate to the task of successfully increasing awareness. Indeed, even the current methodology used for training and education in the responsible conduct of research — including the concept of dual use — have come under increased scrutiny and criticism, as discussed above.

Route Four: The Biodefense Certificate Programme

Faculty of the Center for BioDefense developed a certificate programme in biodefence for its PhD, MD and MS students. The programme comprises five

27 United States Department of Labor, Occupational Safety & Health Administration 1970, *Occupational Safety and Health Act of 1970*, available: http://www.osha.gov/SLTC/laboratories/standards.html.
28 Environmental Protection Agency 1986, *Emergency Planning and Community Right-to-Know Act of 1986*. available: http://frwebgate.access.gpo.gov/cgi-bin/usc.cgi?ACTION=BROWSE&TITLE=42USCC116.

compulsory courses and one elective. Of those required are two fundamental biomedical science (specified by the student's degree programme) and three biodefence-specific courses. The first of the latter is a weapons-survey course: biological and toxin agents are reviewed with respect to virulence, pathogenesis, route of infection/intoxication, treatment, history and potential use. The second focuses on the molecular biology of select agents (bacteria and viruses) and focuses on key papers, both classic and in current literature. The students read and analyse the science and policy implications of studies such as the three iconic papers describing (1) the mousepox IL-4 virus,[29] (2) the 1981 flu reconstruction,[30] and (3) the botulinum contamination of the milk supply.[31] The third is a seminar on contemporary topics, in which students are asked to prepare and discuss current issues in biodefence research, policy and history, including ethics, the responsibility of scientists as citizens, and so on. These courses contain extensive sections on dual-use analysis of contemporary topics in biodefence research. The primary question here is whether this thorough examination of the issues would be impractical for all researchers, either during or after PhD/MS awards. In the current climate of steadily increasing regulatory and compliance requirements, the answer would likely be 'yes'.

Route Five and the Challenges Ahead

In the current climate made competitive by limited funding, and in the absence of a federal mandate, we find concerns among many of the faculty over the possible introduction of dual-use awareness training, consistent with points made by the joint letter to the NSABB from a coalition of scientific societies discussed previously.[32] Many researchers feel they have little time to spend on anything other than the overwhelming demands of staying competitive in contemporary research. A common complaint is that there are many regulatory and compliance requirements in place that encumber the effective progress of science; adding another layer of regulation will be met with dismay by many scientists. Others are troubled by what they consider insufficient guidance on both the definition of 'dual use' and the consequences of a positive identification. Exactly what is dual-use research, and, if one's work is determined to be of dual-use 'concern', what then? There are fears that there is not enough expertise to

29 Jackson, R. J., Ramsay, A. J., Christensen, C. D., Beaton, S., Hull, D. F. and Ramshaw, I. A. 'Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox', *Journal of Virology*, vol. 75, pp. 1205–10.

30 Perrone, L. A. S. and Tumpey, T. A. 2007, 'Reconstruction of the 1918 pandemic influenza virus: how revealing the molecular secrets of the virus responsible for the worst pandemic in recorded history can guide our response to future influenza pandemics', *Infectious Disorders Drug Targets,* vol. 7, pp. 294–302.

31 Wein, L. M. and Liu, Y. 2005, 'Analyzing a bioterror attack on the food supply: the case of botulinum toxin in milk', *Proceedings of the National Academies of Sciences*, vol. 201, pp. 9737–8.

32 Joint letter, 18 July 2008 (see note 7).

anticipate the possible dangers of certain experiments; some think the Australia group should have been able to predict that the IL-4 recombinant ectromelia virus would have a lethal phenotype.[33]

There is a logical connection between dual-use awareness and the generation of a 'pledge' or 'code of conduct'.[34] Although this is outside the scope of the present discussion, we have found that many scientists who think about the dual-use dilemma and an associated code of conduct inevitably arrive at the issue of whistleblowing and whistleblower protection. Might the development of a 'Culture or Responsibility' lead to a culture of accusation and suspicion? A related issue that arises frequently is that of liability: if an entity recognises an experiment or line of inquiry as being of dual-use potential, what is the responsibility of the funding agency or institution sponsoring the research in the event that the information or reagent does lead to a biocrime, a terrorist incident or even a catastrophic event? Indeed, these critical questions were raised in response to the NSABB's 2008 *Strategic Plan*.[35]

Despite these concerns, we have detected a gradual thaw in attitudes toward dual use over the past decade. The RCR course discussion of dual-use experiments of concern has been received eagerly across the university's several campuses. The IBC of UMDNJ in Newark is thinking energetically about ways to incorporate dual-use issues into our review. Some of our colleagues are finally willing to include dual-use questions embedded within larger exam questions in immunology and infectious-disease courses. The University's Department of Environmental and Occupational Health and Safety Services — an arm of the administrative branch — has embraced the issue and recognised the importance of disseminating information and resources. Our next step will be to recruit interested faculty in each department and begin to introduce seminars on dual use as regular yearly or twice-yearly events. We will focus on faculty who are already committed to teaching and mentoring. Our feeling is that discussions can be introduced at many different levels across the institution, creating a 'web of instruction'. Gradually, an appreciation of the complexity of the dual-use dilemma will become part of the scientific idiom.

33 Muellbacher, A. and Lobigs, M. 2001, 'Creation of killer poxvirus could have been predicted', *Journal of Virology*, vol. 75, pp. 8353–55.

34 Atlas and Dando 2006, op. cit.

35 Joint letter, 18 July 2008 (see note 7).