Professional and Graduate-Level Programs on Dual Use Research and Biosecurity for Scientists Working in the Biological Sciences

Workshop Report

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Executive Summary

Since 2001, there has been a flurry of activity in the United States and international community regarding oversight of dual use life sciences research. Dual use research is defined as beneficial research that may be directly misapplied for malicious purposes. The National Science Advisory Board for Biosecurity was established in 2004 to develop recommendations to the federal government for oversight and education of use research in the United States. The 2008 Biological Weapons Convention Meetings of Experts and State Parties addressed oversight, awareness and education of dual use research and codes of conduct to prevent misuse of advancing biotechnologies. The United Kingdom has recently started asking researchers seeking grants if they have considered the dual use implications of their research. The InterAcademy Panel issued a statement providing principles for codes of conduct. Researchers at the Australian National University have advocated mandatory education and training for scientists about the dual use dilemma. The Israeli government recently passed a law regarding dual use life sciences research. Most recently, the report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, entitled *World at Risk,* calls for mandatory education of life scientists about dual use research and biosafety. The recommendations found in this AAAS workshop report could guide the activities and/or policies of the federal government, scientific organizations, research institutions, and the international community on educating those working in the biological sciences on dual use research.

Two units of AAAS—the Center for Science, Technology and Security Policy and the Program on Scientific Freedom, Responsibility and Law – have conducted a study of existing education programs for scientists that address dual use research and/or biosecurity. The **goals** of this study were:

- to document and describe existing educational programs and materials on biosecurity and dual use research for scientists (information provided by course instructors);
- to provide recommendations for developing an educational program on dual use research; and
- to highlight major challenges in developing and implementing educational initiatives on biosecurity-related issues.

With the help of the Association of American Universities and university professors and administrators, we identified fourteen programs that specifically dealt with educating graduate or professional students in the biomedical sciences on dual use research issues. We convened a group of experts in responsible conduct of research, bioethics, the life sciences, and biosecurity on November 21, 2008 at AAAS to review these educational programs and provide recommendations on how best to design and implement similar programs. The existing programs discussed at this workshop educate graduate students working in the biological sciences about dual use research within the context of responsible conduct of research.

In this workshop report, "scientists" refer to undergraduate and graduate students, laboratory technicians, post-doctoral fellows, and principal investigators in the life sciences, chemistry, physics, engineering, medicine, veterinary medicine, nursing, and public health who conduct biological research. This workshop is one of four workshops on biosecurity education; the other three workshops will address biosafety, bioterrorism preparedness and biodefense policy.

Workshop Summary

At the AAAS workshop, participants discussed the benefits and challenges of educating graduate and professional students on dual use research via a range of educational methods and contexts. There was clear consensus at the workshop that students learn best by active learning methods – including real-life simulations, case studies using real examples, small group discussions, and mentorship; that all scientists have a responsibility to consider the societal consequences of their research; and that funding is needed to develop and implement programs to educate scientists about the dual use dilemma.

Several tools (internet-based case studies or modules), methods for teaching (case studies, simulations, and small group discussions) and educational contexts (biosafety programs, mentorship, and responsible conduct of research) currently exist for educating students about dual use research. Topics to cover in education programs range from a focus on the dual use dilemma to a broad array of information regarding biological weapons, biosecurity, bioethics, and dual use issues. Participants did not agree on a preferred method for teaching, but instead supported the idea that these programs should be flexible and allow institutions to tailor their program to best suit their researchers.

Workshop participants highlighted several major gaps and challenges:

- Lack of funding and time for development and implementation of education programs;
- Low levels of interest and knowledge of the dual use dilemma by senior scientists (the educators) and institutional leaders;
- Defining appropriate metrics for the impact of education programs on behavior;
- Shortage of case studies tailored to specific disciplines, such as bioengineering and nanotechnology, and to audiences including non-scientists, such as administrators and the public;
- Lack of educational tools to help scientists develop the skills needed to assess the risks and benefits of their research;
- Absence of data about how much and by whom dual use research is being conducted, and the nature of any ongoing contentious research; and
- Need to identify the target audiences and best approaches to educate them

These gaps in knowledge and challenges should be considered when undertaking the development of educational programs about biosecurity and the dual use dilemma for scientists.

Recommendations

Based on the workshop discussion, there emerged several recommendations for addressing different aspects of education for scientists about the dual use dilemma for the federal government, research institutions, and scientific organizations. Many of these recommendations could also be useful to the international community.

1. **The scientific, ethical, and legal issues related to identifying and addressing issues related to dual use life sciences research should be taught to American and foreign scientists working in the life sciences in the U.S., with due consideration to relevance and flexibility of educational curricula at the institution. This requirement should be accompanied by funding; it should not be an unfunded mandate (see Recommendation 3).**

2. **The identified gaps in knowledge should be addressed. These include:**
    a. **development of tools for educating scientists to assess the risks and benefits of dual use research and technological advances;**
    b. **identification of who is doing research with dual use potential, quantification of how much of this research is being conducted, and the nature of what potentially dangerous research is currently being performed; and**
    c. **development of methods and metrics for assessing dual use education programs.**

3. **The NSABB should recommend that federal agencies conducting or supporting life science research provide funds on a direct cost basis for education on dual use issues.**

4. **The NSABB should recommend general guidance for what scientists should do if they encounter a dual use situation. The federal government should task the NSABB to develop these guidance recommendations.**

5. **The NSABB should develop a resource listing possible topics to cover, and existing methods and materials for teaching about the dual use dilemma for institutions to use when developing their own education programs. The federal government should task the NSABB to develop this resource.**

6. **Scientific organizations, including scientific and engineering societies, should disseminate materials and foster interest about dual use issues within the scientific community.**

7. **Scientific organizations should develop discipline-specific case studies applicable to dual use research beyond the dual use research of concern**

outlined by the NSABB. Scientific organizations should also develop educational materials appropriate for non-scientists and younger students.

8. **Institutions should educate all junior researchers (including research technicians, graduate students, and post-doctoral fellows) about scientific responsibility and the dual use dilemma.**

9. **Institutions should develop education programs on dual use research for scientists and non-scientists.**

10. **Institutions should encourage senior scientists' interest in training and mentoring junior researchers about responsible conduct of research and the dual use dilemma.**

11. **Informed by the NSABB's guidance recommendations, institutions should develop their own guidance for scientists about dealing with dual use concerns and designate an institutional point of contact to consult on dual use research issues if the need arises.**

Report

Background

Many advancements in the biomedical and agricultural sciences can be attributed to beneficial biological research and advancing biotechnologies. Since 2001, there has been a flurry of activity in the U.S. and international community regarding oversight of dual use research in the life sciences. Dual use research is defined as beneficial research that may be directly misapplied for malicious purposes.[1] The National Science Advisory Board for Biosecurity (NSABB) in the United States has recently approved its policy recommendations for education on dual use research;[2] the 2008 Biological Weapons Convention (BWC) Meetings of Experts (August 2008) and States Parties (December 2008) have focused on raising awareness and education of dual use research;[3] and biosecurity experts from the United Kingdom, United States and South Africa have developed or are currently reviewing education materials for dual use research.[4] The Federation of American Scientists (FAS),[5] Southeastern Regional Center of Excellence for Emerging infections and Biodefense (SERCEB),[6] and the Center for Arms Control and Nonproliferation (CACNP)[7] have created online tools for educating scientists about dual use research. As a consequence of the BWC and the NSABB's international outreach activities, many nations throughout the world are beginning to consider educating their biological scientists on dual use research, possibly within the context of research ethics, biosafety or biosecurity. In addition to these activities, the Israeli government recently passed a law regarding dual use life sciences research.[8] Most recently, the report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission), entitled *World at Risk*, calls for mandatory education of life scientists about dual use research.[9]

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[1] This should be distinguished from other definitions of dual use research, such as civilian versus military research.

[2] See http://oba.od.nih.gov/biosecurity/about_nsabb.html for more information.

[3] See http://www.unog.ch/80256EE600585943/(httpPages)/8C24E93C19BDC8C4C12574F60031809F?OpenDocument and http://www.unog.ch/80256EE600585943/(httpPages)/F1CD974A1FDE4794C125731A0037D96D?OpenDocument for more information.

[4] Current activities by nations on developing education materials on dual use life science research were discussed at the November 5-6, 2008 NSABB International Roundtable in Bethesda, Maryland.

[5] The Federation of American Scientist Case Studies can be viewed at http://www.fas.org/biosecurity/education/dualuse/index.html.

[6] The Southeastern Regional Center of Excellence for Emerging Infections and Biodefense dual use module can be viewed at http://www.serceb.org/modules/serceb_cores/index.php?id=3.

[7] The Center for Arms Control and Nonproliferation education module can be viewed at http://www.politicsandthelifesciences.org/Biosecurity_course_folder/base.html.

[8] Bill for the Regulation of Research into Biological Disease Agents, 2008. Israel.

[9] Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism was set up by Congress to assess current activities and provide recommendations for the U.S. to address WMD threats. The Report of the Commission on the Prevention of WMD Proliferation and Terrorism (*World at Risk*) was released in December 2008.

Issues concerning safety and security – including select agent regulations, export control regulations, visas, and the threat of biological weapons – are not foreign to the biological sciences. The select agent regulations and export controls (including deemed exports) affect scientific communication and collaboration. Over the last several years, the select agent program and export control regulations attempt to prevent transfer or acquisition of specific biological agents and dual use knowledge or equipment by unauthorized or nefarious individuals, which is a major concern of the international security community. This concern affects business practices within the industrial sector and collaborations and communication among academic scientists. Select agent regulations also affect collaborations with public health practitioners or scientists in less developed countries since they may not be able to afford proper physical security or safety training as in Western nations. Visa problems also affect collaboration and communication, hence impinging upon American scientific advancement. These problems, while not necessarily related to dual use research, influence the way science is conducted in the U.S. and abroad, and may be useful topics to discuss, along with dual use research, with scientists to help further their understanding of the balance between national and international security concerns and scientific advancement.

Most of the offensive biological weapons programs ended before or at the time of the signing of the Biological and Toxin Weapons Convention (BWC) in 1972.[10] The BWC prohibited the development, production, stockpiling, acquisition or retention of harmful biological agents "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes" and methods for weaponization of these agents.[11] Despite being a major signatory to the BWC, however, the Soviet Union had an extensive, covert offensive program that was revealed in the early 1990's.[12] Subsequently, offensive programs in other nations – South Africa, Iraq and Libya – were revealed.[13] Following the fall of the Soviet Union, the BWC focused on developing a verification protocol to enforce the articles of the treaty. While the verification protocol failed in 2001, the BWC instituted annual meetings between the review conferences to discuss important issues related to the BWC. Among the topics addressed were codes of conduct for practicing scientists (2005 Meetings of Experts and States Parties);[14] oversight, awareness, and education of dual use research (2008 Meetings of Experts and

[10] This treaty built on the Geneva Protocol (1925) prohibiting the unprovoked use of biological and chemical weapons.
[11] The Biological Weapons Convention treaty can be read at http://disarmament.un.org/WMD/bwc/BWCtext.htm.
[12] Alibek, K, Handelman, S. *Biohazard*. Bantam Books. 1999.
[13] See http://cns.miis.edu/research/cbw/possess.htm for more information.
[14] See http://www.unog.ch/80256EE600585943/(httpPages)/DA292636AE31F1CBC125718600361E55?OpenDocument for more information.

States Parties); and biosafety guidelines for high containment laboratory research (2008 Meetings of Experts and States Parties).[15]

It is also worth noting that national and international scientific associations and academies – American Society for Microbiology,[16] American Medical Association,[17] International Union of Microbiological Societies,[18] Royal Netherlands Academy of Arts and Sciences[19] – have developed or are considering development of codes of conduct for their members on their responsibilities on the possible misuse of their research.[20] Codes of responsible conduct could be topics of discussion in education programs that teach scientists about dual use research.

In the 1970's, the American scientific community called for a moratorium on the newly emerging recombinant DNA (rDNA) technology until the technology's risks (including its potential to be misused for malicious purposes) could be assessed and guidelines were formed regarding the safe use of rDNA.[21] Preeminent American scientists, government officials and journalists came together to discuss the risks of this emerging biotechnology at the Asilomar Conference in 1975.[22] These actions resulted in the creation of guidelines outlining the safe use of rDNA as well as new oversight bodies at all academic institutions funded by the National Institutes of Health (NIH). These bodies - Institutional Biosafety Committees (IBCs) - are registered with the NIH Recombinant DNA Advisory Committee. Several companies and international research institutes voluntarily established IBCs to review the risk of rDNA research at their facilities. Current policy discussions in the U.S. regarding oversight of dual use research in the life sciences resemble discussions that promoted the safe use of rDNA and support the review of potential dual use research at the laboratory (principal investigators) and institutional (IBCs) levels before federal review. In the United Kingdom, the three major granting organizations – Wellcome Trust, Medical Research Council, Biotechnology and Biological Sciences Research Council – all require applicants to consider the dual use implication of their proposed research, similar to that required for rDNA.[23] The European Union grant review process also includes reviewing potential security implications of

[15] See http://www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC12572BC00319612?OpenDocument for more information.
[16] See http://www.asm.org/ASM/files/ccLibraryFiles/FILENAME/000000001596/ASMCodeofEthics05.pdf.
[17] See http://biosecuritycodes.org/docs/AMA%20Code.pdf.
[18] See http://www.iums.org/about/Codeethics.html.
[19] See http://www.knaw.nl/publicaties/pdf/20071092.pdf.
[20] For a list of codes of conduct for biosecurity, visit http://biosecuritycodes.org/codes_archive.htm.
[21] Berg, P. Meetings that Changed the World: Asilomar 1975: DNA Modification Secured. *Nature*. 18 Sept 2008. 455: 290-291.
[22] See http://nobelprize.org/nobel_prizes/chemistry/articles/berg/index.html for more information.
[23] See http://www.mrc.ac.uk/consumption/groups/public/documents/content/mrc002538.pdf for more information.

proposed life science research.[24] While the U.S. has not yet instituted similar procedures, these are areas under active consideration.

While many life scientists are mostly unaware of the BWC, they became acutely aware of other issues, like human subjects research, during the latter part of the 20th century. Following several cases describing scientific fraud and misconduct, Congress and the scientific community began discussing issues of scientific integrity in the health sciences.[25] During the mid-1980's, The Association of American Universities (AAU), Association of American Medical Colleges (AAMC), AAAS, the University of Michigan, and Harvard University were among the first to support investigating allegations of scientific misconduct and recommend or institute programs for promoting high ethical standards among life scientists. In 1985, Congress passed the Health Research Extension Act, which required the Department of Health and Human Services (HHS) to institute policies on receiving and reviewing incidents of scientific fraud. In 1989, the Institute of Medicine released a report, *The Responsible Conduct of Research in the Health Sciences,* which recommended that the National Institutes of Health (NIH), university administrators, and professional societies develop and implement educational materials encouraging scientists to conduct their work using the highest ethical and professional standards. Later that year, the Office of Scientific Integrity and Office of Scientific Integrity Review were created; these offices were later consolidated in 1992 as the Office of Research Integrity (ORI). ORI supports development of educational materials to train scientists about responsible conduct of research (RCR) and reviews allegations of research misconduct.[26] RCR training can include data acquisition, management, sharing, and ownership; conflict of interest and commitment; human subjects research; animal welfare; research misconduct; publication practices and responsible authorship; mentor/trainee responsibilities; peer review; and collaborative science. In addition to these traditional topics, universities often include other relevant ethics topics in their RCR program (Figure 1). Programs that receive NIH training grants are required to provide RCR training; the National Science Foundation is considering RCR training for grants it funds. This could be an effective educational context for training scientists on dual use research and/or other biosecurity issues.

As indicated above, the U.S. and the international community, from the BWC and the United Nations to individual nations and non-governmental organizations, are interested in educating their scientists about dual use research. Whether classes, workshops, lectures, or online modules, the structure and delivery of education programs will most likely differ among nations and disciplines to reach target audiences effectively. Some programs could address dual use research by itself or within the context of biosecurity, biosafety or bioethics. While the content (and language) may differ among education programs globally, the ability to demonstrate the need for these programs to scientists, to

[24] The European Union grant review for dual use concerns was discussed at the November 5-6, 2008 NSABB International Roundtable in Bethesda, Maryland.
[25] See http://ori.dhhs.gov/about/history.shtml and the 1989 Institute of Medicine report, *The Responsible Conduct of Research in the Health Sciences,* for more information.
[26] See http://ori.hhs.gov/ for more information.

make the programs relevant to target audiences, and to demonstrate the effectiveness of these programs are all important considerations for any education program designed to teach scientists about dual use research.[27]

The AAAS Project

Through its interactions with the scientific and policy communities, AAAS is uniquely qualified to help identify and assess existing education programs for scientists on dual use research and provide recommendations to research institutions, government policymakers and scientific organizations for developing and implementing such programs. Two units of AAAS - the Center for Science, Technology and Security Policy and the Program on Scientific Freedom, Responsibility and Law - have conducted a study of existing education programs for scientists that discuss dual use research. The **goals** of this study were:

- to document and describe existing educational programs and materials on biosecurity and dual use research for scientists (information provided by course instructors);
- to provide recommendations for developing an educational program on dual use research; and
- to highlight major challenges in developing and implementing educational initiatives on biosecurity-related issues.

In this report, "scientists" refer to undergraduate and graduate students, laboratory technicians, post-doctoral fellows, and principal investigators in the life sciences, chemistry, physics, engineering, medicine, veterinary medicine, nursing, and public health who conduct biological research. This workshop is one of four workshops on biosecuriy education; the other three workshops will address biosafety training, bioterrorism preparedness and biodefense policy.

Methods

Existing programs on educating scientists about dual use life sciences research were identified through a formal Internet-based survey sent to Deans at American colleges of medicine, veterinary medicine, nursing, public health, engineering, and graduate schools of arts and sciences (including physics, engineering, chemistry, bioinformatics, and the life sciences). We thank the Association of American Universities for its help in fielding the survey to its membership, which includes sixty top research institutions in the U.S. In addition to collecting information from the survey, we conducted our own search of programs using the internet and word-of-mouth associations. We identified four

[27] These concerns were discussed at the November 5-6, 2008 NSABB International Roundtable in Bethesda, Maryland.

categories of educational programs: education programs for scientists, biodefense policy courses, biosafety training programs, and bioterrorism preparedness courses for public health students. The workshop described in this report was focused on the education programs for scientists.

Education Programs for Scientists

To date, we have identified fourteen programs, primarily for graduate students in the life sciences, in the United States. (Table 1) We held a workshop on November 21, 2008 at AAAS in which a group of experts in biosecurity, bioethics, the life sciences, and responsible conduct of research were convened to review current education programs on dual use research and discuss how future programs can be designed and implemented. The agenda, questions asked, and lists of speakers and participants are included in the Appendix. Workshop reading material was provided in advance to each attendee.[28] Government representatives from the Department of Health and Human Services (NSABB, ORI, NIH Office of Intramural Research, and Office of the Assistant Secretary for Preparedness and Response), Department of State, White House Homeland Security Council, and the Office of the Director of National Intelligence also attended the workshop.

We invited instructors to discuss their educational programs with the group, and workshop participants raised questions about the content of the discussed programs, the level of understanding by students, the audience, and challenges of designing and implementing the program. Along with these discussions, workshop attendees were asked to consider other educational offerings that were identified by AAAS before considering possible recommendations for designing and implementing an educational program. International as well as U.S. education initiatives were discussed.

Workshop Summary

At the AAAS workshop, participants discussed the benefits and challenges of educating graduate and professional students on dual use research via a range of educational methods and contexts. There was clear consensus from the workshop that students learn best by active learning methods – including real-life simulations, case studies using real examples, small group discussions, and mentorship; that all scientists have a responsibility to consider the societal consequences of their research; and that funding is required to develop and implement programs to educate scientists about the dual use dilemma.

The workshop commenced with an overview of the NSABB's current activities for outreach and education on dual use issues by Dr. Kathryn Harris (NSABB contractor), followed by a presentation on responsible conduct of research (RCR) programs by Dr.

[28] AAAS set up a workshop website with reading material in addition to providing lectures at the workshop. See http://cstsp.aaas.org/Biosecurity_Workshop/; userid: dual_use_education; password: documents.

Michael Kalichman (University of California, San Diego). The subsequent discussion highlighted several challenges related to the development and implementation of RCR programs at academic institutions, including the availability of funding, the lack of interest by many (not all) senior scientists, time constraints, and measurability of impact. Dr. Kalichman as well as other participants also noted that of the nine core RCR themes listed by the ORI, only human subjects research, animal welfare and research misconduct are required of all American students funded by training grants from the NIH (Figure1).

Following this introductory panel, Dr. Robert Cook-Deegan (Duke University) discussed his lecture, "Responsible Genomics," which includes a discussion about the importance of dual use issues and their historical significance. The students in his course, who are in policy as well as the life sciences, are assigned the SERCEB online module prior to class and review papers or actual research proposals with dual use implications in class. Dr. Cook-Deegan does not formally give his students exams, but rather attempts to raise awareness among students within his course. Dr. Michael Imperiale (University of Michigan; NSABB member) lectures on dual use research within the RCR framework. The students, which include all graduate students and post-doctoral fellows on NIH training or K grants,[29] watch a podcast of a past lecture and participate in small group discussion during class. In these small groups, students discuss the definition of dual use research, risks and benefits of conducting and communicating research, and the global nature of science and emerging technologies. Dr. Imperiale also encourages his students to discuss the dual use dilemma with their colleagues. The final speaker in this panel, Dr. Marie Isabelle Chevrier (University of Texas, Dallas) discussed her collaborative project with Brian Rappert, Ph.D. (University of Exeter, UK) and Malcolm Dando, Ph.D. (University of Bradford, UK) that focuses on teaching through simulation of actual incidents. Each student is given a role to play, that role's perspective and a written description of the scenario. The students are encouraged to respond according to their assigned role, but have opportunities to voice their own opinions at the end of the simulation.

For the final panel, James Revill (University of Bradford, UK) and Giulio Mancini (Landau Network – Centro Volta, Itlay) discussed their findings from a recent study evaluating course material for biosecurity, biosafety and dual use research at major universities across the European Union. Many of the conclusions from their evaluation, "Fostering the Biosecurity Norm: Biosecurity Education for the Next Generation of Life Scientists,"[30] and subsequent meeting[31] highlight similar challenges for implementing dual use education programs in the United States – notably competing interests, societal

[29] The K grant is an NIH career development grant that is awarded to post-doctoral fellows who are or will be transitioning into a full-time faculty position. For more information, see http://grants1.nih.gov/training/careerdevelopmentawards.htm.
[30] See http://www.centrovolta.it/landau/content/binary/LNCV%20-%20BDRC_Fostering%20Biosecurity%20Norm.pdf.
[31] See http://www.centrovolta.it/landau/2008/11/07/FosteringTheBiosecurityNormAnEducationalModuleForLifeSciencesStudents.aspx.

concerns, and limited resources (including content and teaching tools). Dr. Brian Rappert discussed the seminars he offers in collaboration with Dr. Malcolm Dando. They have hosted and moderated faculty seminars on dual use research in university life science departments in fourteen countries. Each talk presents actual scenarios and encourages peer discussion. In each seminar, Drs. Rappert and Dando asked questions designed to challenge the audience's views on dual use research in order to move the discussion from agreement to disagreement. This was done to highlight the possible ambiguities involved in evaluating the dual use potential of certain types of research. In a number of the seminars, Drs. Rappert and Dando found that many senior scientists were unaware of the term "dual use research."

During the final session of the workshop, all participants were encouraged to review the day's discussion and provide points to consider for designing and implementing an educational program on dual use research. The following section describes points to consider when designing an education program on dual use research and the challenges when implementing such programs.

Points to Consider for Program Design

Workshop participants agreed that students learn best from active learning. As described in the introduction and workshop summary, several tools, methods for teaching and educational contexts exist for educating scientists about dual use research. Participants did not agree on a preferred method of teaching, but instead supported the idea that requirements for these programs should be flexible and allow institutions to tailor their program to best suit their students and faculty. This section first reviews the suggested goals for deciding to develop a program on dual use research, followed by methods for teaching, content, educational context, audience, and challenges for program implementation. The following reflects the collective discussion of the workshop; these views are not necessarily endorsed by AAAS.

- *Goals*

  Goals for education programs, as identified by participants, include stimulating responsible conduct of all scientists and gaining public trust; increasing the awareness and knowledge of norms, practices and laws; and providing guidance for what actions to take and who to contact when a potential dual use concern arises. A few participants suggested that research institutions should strive to proactively develop education programs on dual use research. Many participants supported development of general guidance from the government and institutional leadership on handling cases of potential dual use research of concern that might arise. As an example of guidance, the group was made aware of two pilot programs on ethics consultations

similar to clinical consultations at Johns Hopkins University[32] and Stanford University.[33]

These goals are similar to those for education on RCR topics, such as human subjects research. Unfortunately, senior scientists, many of whom teach RCR lectures, do not always have positive attitudes towards ethics educational programs. One reason could be that these lectures take away valuable time from their research. Unlike the RCR issues, participants agreed that the dual use dilemma is more abstract, which could dissuade senior scientists from addressing the topic. However, one participant noted that with an enthusiastic instructor, students were more interested in discussing the dual use dilemma. To encourage a more positive attitude among senior scientists towards teaching about the dual use dilemma as well as other ethical issues, all scientists need to understand that they have a responsibility to the larger society since the public essentially determines the success of the life science enterprise (via Congressional appropriation), and wants assurances that scientists are conducting research responsibly. The public, on the other hand, needs to acknowledge the important role(s) that science plays in their daily lives. One participant suggested that scientists must also be reminded that they are members of the public as well.

- *Teaching Methods*

To reiterate, participants believed that active learning is the most effective way to educate students about ethical or societal dilemmas. While participants were interested in the use of simulations to teach ethical concerns, they agreed that scientists may not be very receptive to it, especially if overused. Instead, the most widely used methods were case studies and interactive, small group discussions. Participants noted that using actual rather than fictitious scenarios was most effective for both simulations and case studies. SERCEB and FAS have developed online modules that contain case studies, although the SERCEB module presents a fictitious scenario. Both modules have been used in the classroom to promote awareness and discussion of the dual use dilemma. A major problem with current case studies, however, is that they focus on the dual use research of concern as described by the NSABB (Figure 2) and the National Research Council report, *Biotechnology Research in an Age of Terrorism.*[34] Other biological experiments, like development of aerosolization techniques to improve vaccine or drug delivery, also have dual use potential but are not included in the NSABB dual use research of concern. Furthermore, case studies may be used in high schools and colleges in addition to graduate and professional schools. Thus, participants agreed that there is a need for a broader range of case studies that are appropriate for the educational level of

[32] Taylor, H.A. and Kass, N.E. "Our Two Cents: Research Ethics Consultation at the Johns Hopkins Bloomberg School of Public Health." *American Journal of Bioethics*. March 2008. 8(3): 33-35.
[33] Cho, M.K., Tobin, S.L., Greely, H.T., McCormick, J., Boyce, A., and Magnus, D. "Research Ethics Consultation: The Stanford Experience," *IRB: Ethics and Human Research.* 2008. 30(6).
[34] The NRC report, *Biotechnology Research in an Age of Terrorism*, (also referred to as the Fink Report) can be accessed at http://www.nap.edu/catalog.php?record_id=10827.

students as well as those that feature experiments not included by the NSABB's criteria dual use research of concern.

- *Content*

Topics covered in existing programs range from programs that solely focus on the dual use dilemma to programs that also cover the history of biological weapons and biosecurity. The participants' views varied just as much. Participants suggested that programs should use a broader definition of dual use research, rather than that given by the NSABB, and include advancing biotechnologies. The NSABB is mandated to provide recommendations only for scientists working in the life sciences. The dual use research of concern as outlined by NSABB is rooted in microbiology and does not necessarily include other emerging technologies, like nanotechnology, systems biology, bioinformatics, and neuroscience, which may also have dual use potential. Other topics to include in an education program on dual use research are national laws and international obligations (e.g. the select agent regulations, export control laws and the BWC); codes of conduct and professional norms; professional responsibility, including ethical considerations of scientists participating in former state-sponsored biological weapons programs (general or nation state-specific); basic ethical decision-making; ways to communicate research activities to other scientists and the public; and risk/benefit assessment of their research. Participants highlighted the challenges of teaching scientists how to assess the benefits and risks of their research to determine whether to proceed with an experiment, especially when asked to evaluate the threat of how their research can be "directly misapplied."

- *Educational Context*

The educational programs we identified were part of ethics or responsible conduct of research programs. There was no consensus, however, among workshop participants about whether the dual use dilemma should be taught in RCR courses, biosafety training programs, the laboratory, a generic course on dual use technologies, or a combination of these contexts.

Responsible conduct of research. ORI lists nine topics of research ethics with which scientists should be familiar (Figure 1);[35] In addition to these traditional topics, universities often include other relevant ethics topics in their RCR program. However, only three of those topics are required for American graduate students funded by an NIH training grant. Foreign nationals are not required to take the RCR courses. Departments and universities can choose which of the remaining six topics they would like to offer students. Even with funds from ORI for RCR resource and course development, very little funding is available for all institutions to fully develop such courses. Furthermore, there are no good measures for evaluating the impact of RCR courses on scientists' behavior. ORI does compile statistics for research misconduct cases but this is not an ideal metric for determining the impact of RCR programs on behavior.

[35] See http://ori.dhhs.gov/education/.

One participant proposed that RCR programs should consist of one course that includes all nine topics and dual use research. When educating scientists about issues like human subjects research, there are concrete historical examples of unethical behavior to convince scientists of the issue's importance. However, there are no examples that instructors can use to demonstrate to students that their beneficial research could be misapplied for malicious purposes. While there are examples of scientists participating in state-sponsored weapons programs, workshop participants considered these examples as different from the dual use issue.[36] A gap exists in our knowledge about who is doing potential dual use research, what contentious research is currently being performed, and how much of this research is being conducted. This information may be helpful in convincing scientists of the importance of understanding their responsibility related to the dual use dilemma.

Biosafety. In many countries, the terms 'biosecurity' and 'biosafety' have the same meaning,[37] which may be one reason why the NSABB is considering recommending that biosecurity and dual use education be combined with biosafety training. In its December 2008 report, the WMD Commission recommended that biosafety and biosecurity be combined into a unified "laboratory risk management" framework and that education activities on this framework for life scientists should be mandatory.[38] In fact, the 5th Edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) has a section on biosecurity.[39] Emory University's biosafety training program has also incorporated a dual use research component for those being trained in laboratory biosafety level (BSL) 3 and 4.[40] Although this seems like an attractive context for educating scientists about the dual use dilemma, only scientists working in high-

[36] Scientists working in offensive biological weapons programs are intentionally developing harmful agents for easy dissemination whereas scientists conducting legitimate biological research whose knowledge, tools or techniques could be misapplied don't intentionally make weapons or know who may want to use their research to develop biological weapons.

[37] The World Health Organization (WHO) defines laboratory biosecurity as "protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release," and laboratory biosafety as "the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release." (WHO *Laboratory Biosafety Manual*, 3rd Edition, 2004). While these terms are distinct in the United States and by the WHO, many countries "construe 'biosafety' to include or to be synonymous with 'biosecurity.'" (Saleno, RM and Koelm, JG. Biological Laboratory and Transportation Security and the Biological Weapons Convention. Sandia National Laboratories Report 2002-1067P, 2002).

[38] The WMD commission also recommends that federal agencies provide funds for development of educational materials. Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. *World at Risk*. December 2008. (See http://www.preventwmd.org/report/).

[39] For the entire manual, visit http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf. To view the section on biosecurity, see http://www.cdc.gov/OD/ohs/biosfty/bmbl5/sections/SectionVI-PrinciplesofLaboratoryBiosafety.pdf.

[40] For more information about the biosafety training program, visit http://www.sph.emory.edu/CPHPR/biosafetytraining/index.html.

containment laboratories (BSL 3 and 4) are required to take a formal biosafety training session.

Mentorship. Mentorship by older graduate students, post-doctoral fellows and principal investigators is a critical method of learning as a scientist. To effectively educate scientists about dual use issues, however, there must be general awareness and acceptance of the dual use dilemma within the scientific community. While future generations of scientists can be educated on dual use issues via mentorship, initial efforts may be more effective in the classroom, during biosafety training, or as part of professional development programs.

Generic dual use technologies course. Workshop participants noted that a variety of emerging technologies, not included in the NSABB's dual use research of concern, may also have dual use potential. Some of these, like nanotechnology, neuroscience and bioengineering, are part of the biological research enterprise. Participants suggested that the dual use dilemma as described by the NSABB should be taught along side a broader array of dual use technologies. This course would not necessarily be part of an RCR or biosafety course.

- *Audience*

Although we searched for education programs in graduate schools of arts and sciences (including the life sciences, chemistry and physics) and engineering and professional schools of medicine, nursing, public health, veterinary medicine, and engineering, the programs we identified target graduate students in the life sciences[41] (see Table 1). Workshop participants also listed other potential audiences who would greatly benefit from being educated on the dual use dilemma. The obvious audiences are all hard science students (not just those trained in traditional life science disciplines), post-doctoral fellows, foreign scientists, senior scientists, and instructors of science courses. In addition to these audiences, participants believed educational programs should be provided to non-scientists (such as university administrators), high school teachers and/or students, and undergraduate science students. The programs should, of course, be appropriately tailored for each audience. Participants also considered "training-the-trainer" as useful methods for helping instructors teach a variety of audiences about complex science and society (including security) issues.

- *Gaps in Knowledge and Challenges*

Workshop participants highlighted several major gaps in knowledge and challenges that should be considered when designing education programs about biosecurity and the dual use dilemma for scientists. The most prominent issue is the lack of funding and the time needed for developing and implementing these education programs. This issue is tied very closely to the ongoing debate over whether an education program on dual use research should be mandatory or voluntary. The RCR

[41] AAAS also identified programs on biodefense policy, bioterrorism preparedness, and biosafety. Similar AAAS workshops addressing these categories of programs will occur in 2009.

experience has demonstrated that these programs are an unfunded mandate. Workshop participants noted that this same problem will also be a challenge for dual use education programs, regardless of whether or not the program is mandated by the federal government, if proper funding is not allotted.

Since the AAAS workshop, three documents - the WMD Commission report, *World at Risk*;[42] the U.S. statement at the 2008 BWC Meeting of States Parties;[43] and the NSABB's recommendations on education of dual use research of concern[44] - have been released that recommend mandatory training of life scientists on dual use research. Only the *World at Risk* report calls for government funding in its recommendation for mandatory education programs on dual use research and biosafety.

Several participants noted that the attitudes of senior scientists towards ethics training greatly influence the perceptions of graduate students and junior scientists about the issues. Given the many bureaucratic demands placed on scientists, adding another educational program to their agenda may not be well received. The challenge here is to encourage senior scientists and institutional leaders to raise awareness of the dual use dilemma as one of many important societal concerns to which scientists must be sensitive in order to improve public trust in the life science enterprise. Scientists must understand they are part of the public, and it is the public that determines their fate with regard to research priorities and government funding.

Similar to RCR courses, measuring the impact of dual use education programs on scientists' behavior is very challenging. This challenge mimics issues experienced by the national security community, where a negative outcome is desired but very hard to measure. Developing valid and reliable measures is needed, but likely to present a daunting task.

Currently available tools, such as the SERCEB and FAS modules, address only the NSABB's dual use research of concern. Many more technologies and scientific disciplines could have dual use potential. Identifying scientists who should be educated and developing educational materials appropriate for their area of research is needed.

As technology advances, there will be an ongoing need to evaluate these technologies for their dual use potential. Scientists will need to be equipped with the skills to assess the risks and benefits of these technological advances to protect against misuse of their work.

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[42] See http://www.preventwmd.org/report/.
[43] See http://www.unog.ch/80256EDD006B8954/(httpAssets)/5F9753D23F2217DDC1257512006004FE/$file/BWC_MSP_2008-USA-081201-AM.pdf.
[44] The approved document will be published at http://oba.od.nih.gov/biosecurity/biosecurity_documents.html.

Recommendations

Based on the workshop discussion, we formulated several recommendations for the federal government, research institutions, and scientific organizations in addressing different aspects of education of scientists about dual use research. Workshop participants suggested that AAAS may be a plausible host for a database of existing tools and programs as well as a resource for helping institutions develop education programs.

Anyone designing or implementing an education program should consider the following recommendations. Many of these recommendations could also be useful to the international community:

1. **The scientific, ethical, and legal issues related to identifying and addressing issues related to dual use life sciences research should be taught to American and foreign scientists working in the life sciences in the U.S., with due consideration to the relevance and flexibility of educational curricula at the institution. This requirement should be accompanied by funding; it should not be an unfunded mandate (see Recommendation 3).**

2. **The gaps in knowledge identified in the previous section should be addressed. These include:**
    a. **development of tools for educating scientists to assess the risks and benefits of dual use research and technological advances;**
    b. **identification of who is doing research with dual use potential, quantification of how much of this research is being conducted, and the nature of what potentially dangerous research is currently being performed; and**
    c. **development of methods and metrics for assessing dual use education programs.**

The NSABB currently has the lead role in recommending policies related to dual use education and oversight to all federal agencies that fund life sciences research. In addition, NSABB work products are shared with the international community at international meetings and the Biological Weapons Convention. Although workshop participants did not support the NSABB developing a curriculum on dual use issues, they did identify a role for NSABB in facilitating or recommending guidelines/policies for the development of education programs. The federal government and the NSABB should consider the following recommendations:

3. **The NSABB should recommend that federal agencies conducting or supporting dual use research provide funds on a direct cost basis for education on dual use issues.**

4. **The NSABB should recommend general guidance for what scientists should do if they encounter a dual use situation. The federal government should task the NSABB to develop these guidance recommendations**. Examples of guidance that the NSABB has previously recommended include those on oversight and communication of dual use research; these guidance recommendations can be accessed at http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

5. **The NSABB should develop a resource listing possible topics to cover, and existing methods and materials for teaching about the dual use dilemma for institutions to use when developing their own education programs. The federal government should task the NSABB to develop this resource.**

Scientific organizations, including scientific and engineering societies, play a key role in reaching out to and raising awareness of issues important to their members. These organizations should consider the following recommendations;

6. **Scientific organizations should disseminate materials and foster interest about dual use issues within the scientific community.**

7. **Scientific organizations should develop discipline-specific case studies applicable to dual use research beyond the dual use research of concern outlined by the NSABB. Scientific organizations should also develop education materials appropriate for non-scientists and younger students.**

Academic institutions, industry and government laboratories play an important role in developing and implementing educational programs on dual use research. There are several tools, methods for teaching, educational contexts, and content from which institutions can choose to develop education programs to best suit their particular institutional needs. Research institutions should therefore consider the following recommendations:

8. **Institutions should educate all junior researchers (including research technicians, graduate students, and post-doctoral fellows) about scientific responsibility and the dual use dilemma.**

9. **Institutions should develop education programs on dual use research for scientists and non-scientists.**

10. **Institutions should encourage senior scientists' interest in training and mentoring junior researchers about responsible conduct of research and the dual use dilemma.**

11. **Informed by the NSABB's guidance recommendations, institutions should develop their own guidance for scientists about dealing with dual use concerns and designate an institutional point of contact to consult on dual use issues if the need arises.**

Conclusion

The dual use dilemma in the life sciences has been an ongoing area of concern within the security community since the 2001 terrorist attacks and anthrax attacks. Dual use research is beneficial research that could be misapplied for malicious purposes. There are several governmental and intergovernmental activities targeted at raising awareness, education and oversight of dual use research. The AAAS Center for Science, Technology and Security Policy and Program on Scientific Freedom, Responsibility and Law set out to review existing education programs on dual use research and convened a group of experts in biosecurity, bioethics, the life sciences, and responsible conduct of research to discuss these programs, highlight the challenges for designing and implementing education programs on dual use research, and provide recommendations for how to develop those education programs. As noted in the workshop summary, scientists' responsibility with regard to the dual use dilemma is a difficult problem to address, but the recommendations provided by workshop participants should help focus ongoing and future efforts to ensure scientists are acting responsibly and to enhance public trust.

Table 1: Academic Dual Use Research Programs Summaries in the U.S.

Academic Institution	Program/Department	Students	Course/Lecture	Extent of Biosecurity Content
Colorado State University	Department of Microbiology, Immunology, and Pathology	Appears to be directed to practicing scientists	Course: Biosafety in Research Laboratories, Lecture on "Regulated Biosafety and Biosecurity"	Addresses select agent regulations; Also addresses issues with rDNA but nothing explicitly about dual use
Duke University	Center for Genome Ethics, Law and Policy	Pre-requisite is some familiarity with genomics, bioinformatics, or both	Course: Responsible Genomics: Ethical, Legal and Policy Issues in Genomic and Bioinformatics Research; Lecture on Dual-Use Research - Bioterrorism & Public Health	
Johns Hopkins	Berman Institute of Bioethics		Course: Genetics, Ethics and Policy; One lecture that focuses on dual-use technologies	Touches on dual use technologies
Michigan State University	Department of Epidemiology	Epidemiology students, occasionally students from other disciplines incl. veterinary medicine, speech pathology, nursing and others	Course: Nature and Practice of Scientific Integrity; Lecture on balancing academic freedom and national security	Originally began as NIH training grant targeting clinicians to promote research capabilities
North Carolina State University	Department of Philosophy	Humanity and Science students	Lecture: Bioterrorism and the Responsible Conduct of Biomedical Research	Discusses responsibilities related to the dual use issue. Lecture also given to researchers at NIEHS* and the Carolina Area Biosafety Association
Princeton University	Department of Molecular Biology	Possibly undergraduate	Single seminar session on basic ideas of biosecurity e.g. bioterrorism, publication, experiments of concern	Seminar part of an eight-part seminar series
Princeton University	Woodrow Wilson School of Public and International Affairs, Program on Science and Global Security	Policy Students	Course: Protection Against Weapons of Mass Destruction (WMD); Two lectures on Biological Weapons and Biotechnology	Covers dual use experiments of concern
University of California-Berkeley	Department of Molecular and Cell Biology	Undergraduate students	Course: Responsible Conduct of Research	Discusses publishing sensitive findings and dual use research
University of California	Microbiology, Immunology, and Molecular Genetics	Graduate and Undergraduate Students	Graduate course: Ethics and Accountability in Biomedical Research; Lower division course: Biological Threats to Society: Bioterrorism and Emerging Infections	Cover responsibilities and ethical conduct of investigators in research, responsibilities to peers, sponsoring institutions, and society as well as conflicts of interest, disclosure
University of Medicine and Dentistry of New Jersey	Department of Medicine; Graduate School in Biomedical Sciences	Masters and PhD students	Molecular biology of select agents; WMD/biodefense; Responsible conduct of research	Specific lectures on biodefense and dual use; biodefense issues including dual use, arms control and history of WMD; dual use as single topic within NIH training requirement
University of Michigan	Department of Microbiology and Immunology	Graduate and Medical students	Course: Research Responsibility and Ethics; Lecture: Dual Use Research	Involves discussion of case studies; discusses role of NSABB and experiments of concern
University of North Carolina	School of Public Health	Public Health Students		Certificate program and Masters program in disaster management
University of Pennsylvania	Center for Bioethics	4th year medical students; also used lecture for seminar at UVA for students and postdocs in BL3 Lab as part of bioshield grant	Course: Bioethics and Professionalism; Lecture: Biodefense and Bioethics	Discusses biosecurity, publishing, aim of experiment
Virginia Commonwealth University	Molecular Biology and Genetics	Medical Students	Course: Scientific Integrity; Lecture: Authorship and Publication Practices	Touches on Experiments of Concern and Biosecurity Implications; also includes biosecurity-related case-studies

* National Institute of Environmental Health Sciences (NIEHS)

Figure 1: Responsible Conduct of Research (RCR) Education Topics

Office of Research Integrity (ORI) RCR Topics[45]

- Data Acquisition, Management, Sharing and Ownership
- Conflict of Interest and Commitment
- Human Subjects**
- Animal Welfare**
- Research Misconduct**
- Publication Practices and Responsible Authorship
- Mentor / Trainee Responsibilities
- Peer Review
- Collaborative Science

Examples of Additional Topics[46]

- Social Responsibility
- Raising Questions, Addressing Problems
- Dispute Resolution
- Whistleblowing
- Stem Cells
- Environmental Protection
- Agriculture
- Nanotechnology
- Engineering
- Computers and Information Technology
- Biosecurity
- Dual Use Technology
- Arts and Humanities

[45] For more information, see http://ori.dhhs.gov/education/.
[46] These topics were provided by Michael Kalichman in his workshop presentation.
** Required for life science graduate students funded at institutions receiving an NIH training grant

Figure 2: NSABB Definition and Criteria for Dual Use Research of Concern.[47]

Definition:

Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel

Criteria:

1. Is it likely that the research could:
    a. Enhance the harmful consequences of a biological agent or toxin
    b. Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification
    c. Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies
    d. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin
    e. Alter the host range or tropism of a biological agent or toxin
    f. Enhance the susceptibility of a host population
    g. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent

2. Additional Review Assessment
    a. The potential for, and the ways in which, information, technologies, or biological agents from the research could be misused to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel
    b. The likelihood that the information might be misused
    c. The potential impacts of misuse
    d. Strategies for mitigating the risks that information from the research could be misused

[47] NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research.* June 2007.

Appendix

Professional and Graduate-Level Programs on Dual Use Research and Biosecurity Ethics and Responsibility

November 21, 2008
AAAS, Revelle Room (2nd Floor)
9:00 am – 5:00 pm

Agenda

9:00	**Welcome**: Opening Remarks by AAAS
9:15	Review of the National Science Advisory Board for Biosecurity Educational Activities *Kathryn Harris, Ph.D.*, Senior Outreach and Education Specialist (Contractor) NIH Office of Biotechnology Activities Review of Responsible Conduct of Research (RCR) Education and Resources *Michael Kalichman, Ph.D.*, Director, Research Ethics Program University of California, San Diego
10:00-10:15	Break
10:15-12:15	**Panel I: Current U.S. Education Programs** *Robert Cook-Deegan, M.D.*, Duke University *Michael Imperiale, Ph.D.*, University of Michigan *Marie Isabelle Chevrier, Ph.D.*, University of Texas, Dallas
12:15	Lunch
12:45-2:45	**Panel II: International Education Programs** *James Revill and Giulio Mancini*, Landau-Bradford Project on Biosecurity Education *Brian Rappert, Ph.D.*, University of Exeter
2:45-3:00	Break
3:00-5:00	**Discussion on Findings and Recommendations**

Professional and Graduate-Level Programs on Dual Use Research and Biosecurity Ethics and Responsibility

November 21, 2008
AAAS
9:00 am – 5:00 pm

Discussion Questions

- What is the best program design?
  - What is the best educational context (e.g. RCR requirements, seminar courses, labs, etc) for these programs?
  - What content/topics should be included in the program?
  - What resources are already available and what additional resources are needed?

- How can we effectively implement these programs?
  - What are the challenges for implementing these programs?
  - What audience (i.e. disciplines) is appropriate for these programs?

- How do these findings and recommendations fit both domestic and international need?

Professional and Graduate-Level Programs on Dual Use Research and Biosecurity Ethics and Responsibility

November 21, 2008
AAAS, Revelle Room (2nd Floor)

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Professional and Graduate-Level Programs on Dual Use Research and Biosecurity Ethics and Responsibility

November 21, 2008
AAAS, Revelle Room (2nd Floor)

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