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Responsible Conduct by Life Scientists in an Age of Terrorism

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Abstract The potential for dual use of research in the life sciences to be misused for harm raises a range of problems for the scientific community and policy makers. Various legal and ethical strategies are being implemented to reduce the threat of the misuse of research and knowledge in the life sciences by establishing a culture of responsible conduct.

Keywords Dual use · Biological weapons convention · Life sciences · Code of conduct

The Biological and Toxin Weapons Convention (BTWC) establishes an absolute ban on biological warfare and the development of biological weapons[1] (States Parties to the Convention 1972). However, the BTWC lacks verification and compliance protocols and the boundaries between prohibited and allowable activities are sometimes ambiguous. Attempts to establish a legally binding verification/compliance regime failed when the United States rejected a draft protocol saying that the proposed compliance declarations and inspections endangered US economic interests and that the proposed verification protocol would not achieve a real enhancement of national and global security (Bolton 2001; Rissanen 2001). The

[1] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction Article I Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

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United States argued that the BTWC Protocol would be ineffective in stopping would-be proliferators from acquiring an arsenal of biological weapons. The sense of the U.S. position was that the nature of biological weapons defies routine compliance measures—at best there could be confidence building measures, but no real verification would be possible.

While the BTWC lacks legally binding compliance measures, Article IV of the Convention requires that each State Party implement legislation to assure compliance.[2] "This article requires not only the establishment of national penal legislation but measures to enforce implementation as well. Therefore, criminal and civil penalties should be established for persons or entities that violate the Convention, and States Parties should commit to rigorous enforcement of these provisions" (Mahley 2003). The United States enacted the *Biological Weapons Anti-Terrorism Act of 1989*[3] to meet its obligations under the BTWC. This act codifies the prohibition on the development of biological weapons within the U.S.

Although the BTWC establishes the international norm against biological warfare and the development of biological weapons that forms the basis for national implementing legislation, by beginning with development and by allowing biodefense research that is justified for peaceful and prophylactic purposes, it raises a dilemma for the life sciences research community, namely whether there is research in the life sciences that should be prohibited. Given the convergence of research and development (much applied research leads directly to patented inventions) research that aims to develop biological weapons, or that has a high probability of doing so, is legally banned, that is, it qualifies as "forbidden knowledge." Additionally, there is legitimate concern that research in the life sciences permitted by the BTWC, that is, research that is for prophylactic, protective, or peaceful purposes, could lead to the development of biological weapons. Such concern raises the inevitable debate as to whether scientific knowledge is value free and, thus, without bounds, or whether there is "dangerous research" that should not be done and knowledge that should not be openly shared. Sir Francis Bacon, who established the scientific method wrote in his essay, *The New Atlantis*: "And this we do also: we have consultations, which of the inventions and experiences which we have discovered shall be published, and which not; and take all an oath of secrecy for the concealing of those which we think fit to keep

[2] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction Article IV Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

[3] THE US BIOLOGICAL WEAPONS ANTI-TERRORISM ACT OF 1989 Sec. 175. Prohibitions with respect to biological weapons (a) IN GENERAL: Whoever knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so, shall be fined under this title or imprisoned for life or any term of years, or both. There is extraterritorial Federal jurisdiction over an offense under this section committed by or against a national of the United States. (b) DEFINITION: For purposes of this section, the term 'for use as a weapon' does not include the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for prophylactic, protective, or other peaceful purposes.

secret; though some of those we do reveal sometime to the State, and some not" (Bacon 1626). So from the inception of modern science, the community of scientists acknowledged that it needed to act responsibly to protect the public against potentially dangerous scientific information.

The Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats in its report "*Globalization, Biosecurity, and the Future of the Life Sciences*" says: "as with all scientific revolutions, there is a potential dark side to the advancing power and global spread of these and other technologies. For millennia, every major new technology has been used for hostile purposes, and most experts believe it naive to think that the extraordinary growth in the life sciences and its associated technologies might not similarly be exploited for destructive purposes. This is true despite formal prohibitions against the use of biological weapons and even though, since antiquity, humans have reviled the use of disease-causing agents for hostile purposes" (National Research Council 2006). This report, as well as others, such as the National Research Council (NRC) report "*Biotechnology Research in an Age of Terrorism*" (National Research Council 2004) raises the specter that research in the life sciences may be misused for biological weapons development, bioterrorism, and biowarfare—the "dual-use" dilemma.[4] The Interacademy Panel on International Issues (IAP), which is a global network of science academies, echoes this view: "In recent decades scientific research has created new and unexpected knowledge and technologies that offer unprecedented opportunities to improve human and animal health and environmental conditions. But some science and technology can be used for destructive purposes as well as for constructive purposes. Scientists have a special responsibility when it comes to problems of 'dual use' and the misuse of science and technology" (IAP 2005).

But how does one define what research should be done and what should be prohibited or what research findings should be subjected to restrictions or restraints on communication? The difficulty in developing sound approaches for limiting the potential for misuse of research in the life sciences occur in part because virtually all the research of concern is aimed at protecting humankind from disease or otherwise improving the quality of life. Legally binding measures could do harm by constraining research that would improve future human health and well-being. Additionally, research in the life sciences is a global endeavor. Only international accord and widespread concerted national legislation could reduce the threat through laws and regulations. And, unless the scope of research of concern can be defined in such a way that only research of the greatest concern is legally constrained, there inevitably would be a severe impact on the advancement of biomedical knowledge that would be detrimental to humankind.

Starting in 2002, the National Academies Committee on Improving Research Standards and Practices to Prevent Destructive Application of Advanced Biotechnology, headed by molecular biologist Gerald Fink, began to map out a strategy for

[4] The term "dual use" throughout this paper refers specifically to the generation and dissemination of legitimate scientific knowledge that could be misused for biological weapons development and production. It is not here used to refer to research that has a malevolent purpose and is being cloaked behind the guise of legitimate research activities.

responsible action within the scientific community—an effort that it hoped would spread worldwide. This Committee attempted to define the sphere of concern of dual use research for the scientific community by elucidating classes of experiments that it said should be subjected to review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail so as to ensure that the likely benefits outweighed the likely risks of misuse (National Research Council 2004). It identified seven classes of experiments of concern as research that focused on the near term threats of microbial pathogens and toxins. In the longer term, it is likely that other types of threats, including direct human genetic modification and biological modifiers of human behavior, will need to be considered as well (Relman 2006).

Recognizing that some research could result in severe harm if misused, but that most research in the life sciences contributes to the advancement of knowledge for the betterment of humankind, the Fink Committee (National Research Council 2004) endorsed the approach recommended earlier for the physical sciences by the NRC report "*Scientific Communication and National Security,*" also known as the Corson report (National Research Council 1982). This approach of building high walls around a narrowly defined sphere of concern was embodied in National Security Presidential Directive 189 issued by U.S. President Ronald Reagan in 1985 (White House 1985) and, following the terrorist attacks of September 11, 2001, supported by the Assistant to the President for National Security Condoleezza Rice: "…to the maximum extent possible, the products of fundamental research [should] remain unrestricted"…and "where the national security requires control, the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification" (Rice 2001). Classifying research findings places a legally binding barrier around knowledge that is generated, but, given that research in the life sciences, unlike nuclear research, is not born classified, most information of concern would fall into the area of "sensitive but unclassified," that is, information that might be dangerous but that is not legally constrained. Further, the United States would not have a monopoly on research in the life sciences that might be misused. Thus, the most effective means of constraint may need to come from voluntary efforts within the global scientific community to protect scientific knowledge in the life sciences from misuse. This would involve the development of a culture of ethical behavior that takes into consideration national and global security.

The Fink Committee envisaged a living system overseen by a committee of scientists and members of the national security community, which would continuously assess the scientific knowledge that could contribute to biological weapons development, bioterrorism or biowarfare, and, which would seek means of protecting that knowledge from misuse. The National Science Advisory Board for Biosecurity (NSABB) at the National Institutes of Health was established to undertake this task. The NSABB is charged among other things with guiding the development of: (1) A system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns; and (2) Guidelines for the identification and conduct of research that may require special

attention and security surveillance (Office of Biotechnology Activities National Institutes of Health 2004).

Because most life sciences research has dual use potential, the NSABB has sought to delineate a threshold that would identify that subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security, i.e. dual use research of concern.[5] To meet the threshold of being dual use research of concern, the NSABB has proposed that the threat of potential misuse must have broad potential consequences to public health or other aspects of national security, e.g., to threaten populations rather than individuals. The NSABB has also proposed that to be of concern the results of the research would have to have the potential for direct misapplication. This latter requirement effectively invokes the longstanding legal concept of clear and present or clear and imminent danger.[6] The NSABB has suggested that some research in similar areas might rise to this level of concern: Research that (1) enhanced the harmful consequences of a biological agent or toxin; (2) disrupted immunity or the effectiveness of an immunization without clinical and/or agricultural justification; (3) conferred to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitated their ability to evade detection methodologies; (4) increased the stability, transmissibility, or the ability to disseminate a biological agent or toxin; (5) altered the host range or tropism of a biological agent or toxin; (6) enhanced the susceptibility of a host population; or (7) generated a novel pathogenic agent or toxin, or reconstituted an eradicated or extinct biological agent. The NSABB has called upon the U.S. government to establish formal guidelines or a regulatory framework that would govern research that could be defined as dual use research of concern.

Additionally, to advance the responsible conduct of research, the NSABB and other groups have been trying to develop codes of conduct. In its charter, the NSABB is specifically charged with developing "professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in life science research; and materials and resources to educate the research community about effective biosecurity" (Office of Biotechnology Activities National Institutes of Health 2004). Toward that end the NSABB has proposed that individuals involved in any stage of life sciences research have an ethical obligation to avoid or minimize the risks and harm that could result from malevolent use of research outcomes. Specifically the NSABB is recommending that scientists should: (1) assess their own research efforts for dual use potential and report as appropriate; (2) seek to

[5] The proposed criteria for dual use research of concern can be found in a draft report of a working group of the National Science Advisory Board for Biosecurity (NSABB) presented and discussed at the April 19, 2007 meeting of the NSABB. http://www.biosecurityboard.gov/NSABB%20Draft%20DUR%20Ov%20Framewk8%20for%20public%20posting%20041907%20mtg2.pdf.

[6] The clear-and-present-danger doctrine derives from the U.S. Supreme Court in *Schenck v. United States,* 249 U.S. 47, 39 S. Ct. 247, 63 L. Ed. 470 (1919)—"the words are used in such circumstances and of such a nature as to create a clear and present danger that they will bring about the substantive evils that Congress has a right to prevent." IT was later argued that the threshold should be imminent rather than present danger—"produces or is intended to produce a clear and imminent danger that will bring about … certain substantive evils."

stay informed of literature, guidance, and requirements related to dual use research; (3) train others to identify dual use research of concern, manage it appropriately, and communicate it responsibly; (4) serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern; (5) be alert to potential misuse of research. The NSABB is recommending that research organizations and professional societies in the life sciences adopt codes of conduct based upon these principles.

Going beyond U.S. national security concerns, adoption of a code of ethics to govern research in the life sciences is an important way to promote international consensus and to raise the necessary awareness to confront the dual use dilemma globally. The Meeting of Experts of the States Parties to the BTWC meeting in Geneva in June 2005 considered the content, promulgation, and adoption of codes of conduct for scientists. A common theme of those and other discussions has been to develop a code for the life sciences based upon the principle "first do no harm" (Royal Society and Wellcome Trust 2004). But, beyond that principle, which is widely fostered within the medical community, it is proving difficult to achieve consensus. Brian Rappert (2004) has pointed out that attempts to establish codes must address demanding questions about their aims and audience-questions whose answers depend on potentially contentious issues regarding arms control, science, ethics, and politics.

The IAP has issued a statement on biosecurity aimed at providing principles to guide the life sciences community in developing codes of conduct to reduce the risks that research in the life sciences could be misused for bioterrorism or biowarfare (IAP 2005). The 5 principles proposed by the IAP are: "(1) *Awareness*. Scientists have an obligation to do no harm. They should always take into consideration the reasonably foreseeable consequences of their own activities. They should therefore: always bear in mind the potential consequences—possibly harmful—of their research and recognize that individual good conscience does not justify ignoring the possible misuse of their scientific endeavor; refuse to undertake research that has only harmful consequences for humankind; (2) *Safety and Security*. Scientists working with agents such as pathogenic organisms or dangerous toxins have a responsibility to use good, safe and secure laboratory procedures, whether codified by law or common practice; (3) *Education and Information*. Scientists should be aware of, disseminate information about and teach national and international laws and regulations, as well as policies and principles aimed at preventing the misuse of biological research; (4) *Accountability*. Scientists who become aware of activities that violate the Biological and Toxin Weapons Convention or international customary law should raise their concerns with appropriate people, authorities and agencies; and (5) *Oversight*. Scientists with responsibility for oversight of research or for evaluation of projects or publications should promote adherence to these principles by those under their control, supervision or evaluation and act as role models in this regard."

Margaret Somerville and Ronald Atlas (2005) proposed a code of ethics as a weapon to counter bioterrorism with the overall goal of preventing the life sciences from becoming the death sciences through bioterrorism or biowarfare. Under the code, all persons and institutions engaged in any aspect of the life sciences must: "(1) Work to ensure that their discoveries and knowledge do no harm: (i) by refusing to engage in

any research that is intended to facilitate or that has a high probability of being used to facilitate bioterrorism or biowarfare; and (ii) by never knowingly or recklessly contributing to the development, production, or acquisition of microbial or other biological agents or toxins, whatever their origin or method of production, of types or in quantities that cannot be justified on the basis that they are necessary for prophylactic, protective, therapeutic, or other peaceful purposes; (2) Work for ethical and beneficent advancement, development, and use of scientific knowledge; (3) Call to the attention of the public or appropriate authorities activities (including unethical research) that there are reasonable grounds to believe are likely to contribute to bioterrorism or biowarfare; (4) Seek to allow access to biological agents that could be used as biological weapons only to individuals about whom there are reasonable grounds to believe that they will not misuse them; (5) Seek to restrict dissemination of dual-use information and knowledge to those who need to know in cases where there are reasonable grounds to believe that the information or knowledge could be readily misused through bioterrorism or biowarfare; (6) Subject research activities to ethics and safety reviews and monitoring to ensure that (i) legitimate benefits are being sought and that they outweigh the risks and harms; and (ii) involvement of human or animal subjects is ethical and essential for carrying out highly important research; (7) Abide by laws and regulations that apply to the conduct of science unless to do so would be unethical and recognize a responsibility to work through societal institutions to change laws and regulations that conflict with ethics; (8) Recognize, without penalty, all persons' rights of conscientious objection to participation in research that they consider ethically or morally objectionable; and (9) Faithfully transmit this code and the ethical principles upon which it is based to all who are or may become engaged in the conduct of science" (Somerville and Atlas 2005).

An important aspect of this proposed code, as well as the IAP principles, is its interface with codified laws and regulations. It is important that the scientific community assume responsibility for preventing the misuse of science for bioterrorism and biowarfare and that it work with legal authorities when appropriate to achieve this end. Whistleblowing, that is, exposing potential harms to authorities and/or the public, is an important ethical responsibility. As indicated by Somerville and Atlas (2005), providing for "whistleblowing" is an essential element in implementing a code, but establishing a system of responsible authorities to whom concerns can be revealed and ensuring that the whistleblower can be protected from retribution remain major challenges. This aspect of responsible conduct has not yet been adequately addressed by the NSABB. Also, as evidenced in the Thomas Butler case[7] (Enserink and Malakoff 2003), there is a divide between the law enforcement/regulatory communities, which seek to ensure compliance with laws and regulations that have been enacted to prevent dangerous microorganisms being acquired by terrorists, and a well-intentioned scientific community that is trying to find cures for

[7] In January 2003, Thomas Butler reported 30 vials of plague missing from his laboratory at Texas Tech. The Justice Department charged Butler of illegal transportation of plague samples, tax evasion, fraud, and embezzlement. The prosecution of Butler was met with disapproval by many groups of scientists. Despite protests from the scientific community Butler was convicted on 1 December 2003 of 47 of the 69 charges filed against him. Of the convictions, three were for improper shipment of plague samples to collaborators in Tanzania.

diseases. Neither the adequate peer pressure within the scientific community that is needed to ensure full compliance with antiterrorism laws and biosafety/biosecurity regulations (which are viewed by many as excessively restrictive and impeding legitimate science), nor the establishment of a code of conduct to reduce the threat of the misuse of the life sciences have yet to be achieved.

A survey was conducted by the National Academies and American Association for the Advancement of Science to determine the attitudes of practicing American life scientists about dual use research and actions that would be supported by the life sciences community (National Research Council 2009). The survey was overseen by the NAS Committee on Assessing Fundamental Attitudes of Life Scientists as a Basis for Biosecurity. Overall, the survey findings suggest that there may be considerable support for models of oversight that rely on the responsible conduct of research and self-governance by the scientific community. The responses also suggest, however, that there is a critical need to clarify the scope of research activities of high concern and to determine the appropriate actions that members of the life sciences community can take to reduce the risk of misuse of science for biological weapons development and bioterrorism. Many of the respondents indicated that they believe that personal responsibility, including measures such as codes of conduct, could foster a positive culture within the scientific community to evaluate the potential consequences of their research for public safety and national security. They also indicated that they believe that individual researchers, professional scientific societies, institutions, and scientific journals should be responsible for evaluating dual use potential of research and/or fostering the culture of scientific responsibility. The survey found a lack of support for government regulations to control dual use research.

Further efforts to establish a culture of responsibility are needed to ensure fulfillment of the public trust and fiduciary obligations it engenders, and protect against breach, in particular, to ensure that research in the life sciences is not used for bioterrorism or biowarfare (Somerville and Atlas 2005). Awareness is being raised by the very discussion of codes that should enhance the efforts of those in the life sciences to ensure the responsible conduct of science and to protect the scientific enterprise from potential misuse. But, as pointed out by Somerville and Atlas (2005), much more "ethics talk" will be needed to ensure that the "life sciences" do not become the "death sciences." Since it is difficult to separate research done for legitimate purposes from that done for malevolent purposes and because the global scientific community does not have compliance and verification protocols in place, the burden is on the scientific community to self-police and recognize when intent is malevolent or when legitimate research could be subject to imminent misuse. The code(s) will help identify and clarify the responsibilities of all members of the community. The misuse of the life sciences for bioterrorism or biowarfare must be taboo.

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