

Life Sciences or Death Sciences: Tipping the Balance towards Life with Ethics, Codes, and Laws

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Introduction

The search for ethics to govern the life sciences and the threats to public health their misuse could entail, both nationally and internationally, is part of a complex ongoing process which is forcing us to confront diverse and sometimes strongly conflicting viewpoints. To successfully reduce the threat of bioterrorism and biowarfare, and to protect public health, especially on a global level, we all will need to engage across boundaries that have separated us in the past. Only by doing so can we seek to ensure that the promise of our unparalleled discoveries of new knowledge in the life sciences is fulfilled and it's potential for unprecedented harm averted. Certainly, no one measure will be sufficient to ensure that science is not misused, or public health put at risk, or people's rights not unjustifiably breached, but in conjunction with other measures, ethics and law properly used can contribute to the protection of people, the reduction of risks of serious harm, and the deterrence of bioterrorism and biowarfare.

“Ethics and law are related, but they are not the same. Law draws the line we cannot cross without becoming ‘outlaws’. Even if we do not like it, we must nonetheless follow it (while working to change it) or risk... being prosecuted for being an

outlaw...Americans can go to jail for violating the law, but not for violating codes of ethics. We aspire to uphold ethics - we deserve praise (at least some) for behaving 'ethically'; whereas we deserve none for simply following the law, some of which is in fact made up of 'legal technicalities'" (Annas 2006).

In general ethics is used to govern relationships between intimates and law is used to govern relationships between strangers. Today's relationship between science and society is a mixture of trusted friends whom we depend upon for health and well-being, and distant strangers whose motives are often unknown and, sometimes, malicious. Thus, we require new paradigms that encompass laws establishing which activities are prohibited, regulations that safeguard how an inherently acceptable activity is to be carried out in order to avoid foreseeable harm or unreasonable risk, and ethical codes which articulate what may and must not be done if shared societal values are to be honoured (Somerville 2002).

As we consider the legal and ethical approaches that can be employed to help to protect against the misuse of science for biowarfare and bioterrorism we should recognize that the challenges in developing the measures we will need. There is no "one size fits all" approach to the governance of life sciences research and biotechnology (Somerville 2002). The measures we choose to utilize will need to reflect a balance between the necessary certainty (to know what can and what must not be done) and flexibility to be open to universal applicability transnationally. This will, of necessity, involve opening up a critical international dialogue that will help define the boundaries that science must respect to protect against its misuse for bioterrorism and biowarfare and to implement the safeguards needed to protect public health throughout the world.

Legal Prohibitions

The Geneva Convention of 1925 banned the use of bacteriological weapons. Yet France reserved the right to arm itself with biological weapons for retaliatory purposes (Guillemin 2006), invoking the biblical concept of "an eye for an eye." The Biological and Toxin Weapons Convention (BWC) of 1972, however, established an absolute ban

on biological warfare and the development of biological weapons (States Parties to the Convention 1972). It is the only international accord to ban an entire class of weapons. Article I of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction states: “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.” We could regard these prohibitions as a contemporary example of the ancient concept of a taboo. A taboo is one side of a coin the other side of which is the sacred. We can postulate that in our contemporary world we need to develop a concept of the “secular sacred” that protects that which we hold most precious, in particular life, especially human life (Somerville 2006 a).

Despite the BWC norm against biological warfare and the development of biological weapons, there are several problems that arise from its necessary allowance for activities that are prophylactic, protective, or otherwise for peaceful purposes. Many of the activities that would form the basis for biological weapons development are identical to those that could be carried out for permitted purposes. This has allowed several countries, including the former Soviet Union, South Africa, and Iraq to cloak their biological weapons programs within seemingly legitimate facilities, that is, facilities that could have dual uses (Atlas and Dando 2006). In effect the BWC bans a given activity if the intent is to develop biological weapons, but allows that same activity to be carried out if the intent is for peaceful purposes. Because this problem of divining intent has allowed illegitimate activities to go undetected, suspicions are now cast on many presumably legitimate activities, for example, the current U.S. biodefense program.

Although the BWC established the international “legal” norm against the development of biological weapons, it does not include provisions specifying the consequences for failing to meet the obligations of the treaty. As pointed out by Guillemin (2006): “When considering the potential threat of biological weapons in the hands of rogue states or

terrorist groups, security experts tend to assume that scientists will always lend a hand to prevent such nefarious use of their research.” Yet every program to develop biological weapons, including those by the United States, Canada, Britain, and France (prior to the signing of the BWC in 1972), Japan (at the time of World War II), the former Soviet Union (even after their becoming a signatory to the BWC), Iraq (prior to the first Gulf War) , the Aum Shinrikyo, and others, included scientists who were willing to engage in such activities. Despite such violations of the Convention and the international norm against biological weapons development, efforts to establish legally binding verification measures and specific penalties for violating the provisions of the BWC have failed. Essentially it is an international legal agreement without “teeth” since it lacks investigatory powers and specified penalties for violators.

The BWC, however, requires that each State Party implement national legislation to assure compliance, that is, each State Party to the Convention is obliged to enact laws that prohibit activities in breach of the convention and specify penalties for breach. According to Article IV of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, “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.” “This article requires not only the establishment of national penal legislation [to punish breaches of the Convention] but measures to enforce [its] 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).

A number of nations, including the United Kingdom and the United States have enacted legislation codifying the prohibitions of the BWC. The United Kingdom adopted the *Biological Weapons Act 1974* and the United States enacted the *Biological Weapons Anti-Terrorism Act of 1989* to meet their obligations under the BWC. Section 175 of The

US Biological Weapons Anti-Terrorism Act of 1989 provides prohibitions with respect to biological weapons: 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 offence under this section committed by or against a national of the United States.” The definition section states: “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.”

While such national statutes are necessary to implement international conventions in domestic law and useful in deferring the prohibited conduct, they present daunting problems of harmonizing their various provisions with domestic law regarding the definition of crimes, rights of the accused, dispute resolution, and judicial assistance, among other matters. One response to these obstacles has been calls for an international law that would criminalize bioterrorism and the development of biological weapons and allow for extradition (Meselson and Robinson 2004).

Legitimate Research that could be Misused—“Dual Use Research”

Beyond the issue of legally banned activities, there is the dilemma trying to inhibit the potential misuse of knowledge resulting from legitimate research intended to advance scientific knowledge for the public good for biowarfare or bioterrorism. “Because the differences between research on offensive biologic weapons and research on defensive biologic weapons are a matter of degree, not kind, and because biotechnology research is an international activity, any evidence that such research is doing more to put the public at risk than to protect the public will (and should) be especially damaging to the entire enterprise (Annas 2006).” There is legitimate concern that research in the life sciences permitted by the BWC, that is, research that is for prophylactic, protective, or peaceful purposes, could be dangerous and in particular could lead to the development of biological weapons. Such concern raises the inevitable debate as to whether the pursuit of

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. The consensus now, although still opposed by some scientists, is that ethics must be applied to science from its inception – that is, the pursuit of knowledge is not value free and must conform to ethical norms and requirements of society.

Not surprisingly, there have been recurring debates since the tragic events of September 11, 2001, concerning what research should and should not be conducted and what information should and should not be disseminated in the open literature (National Research Council 2004; House of Commons 2003; Journal Editors and Authors Group 2003; Campbell 2006). Scholze (2006), who is in the Division of Ethics of Science and technology at UNESCO, puts it this way: “From the Hippocratic Oath to the Russell-Einstein Manifesto, from Maimonides’ Oath to the Declaration of Geneva (the Physician’s Oath), human history reveals an abundance of pledges guidelines and laws to regulate the relationship between professionals and society. However, increasing concerns about the new and emerging ethical aspects of biomedical research, and its potential for abuse, have led to a surge of ethical debates and their translation into a new, globally accepted codification.” However, not everyone will buy into that codification and, even if we had a globally agreed upon oath for life scientists, the debate over the boundaries for ethically legitimate scientific enquiry will be the subject of ongoing debate.

This is not a new issue. In fact the concern of how to protect scientific knowledge from misuse dates back to the very beginnings of science. 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 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 the abuse of scientific knowledge to do harm.

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 Fink committee report *“Biotechnology Research in an Age of Terrorism”* (National Research Council 2004) raise the spectre that research in the life sciences, especially in molecular biology and informatics, may be misused for biological weapons development, bioterrorism, and biowarfare—the so called “dual-use” dilemma. The inherent dual nature of biodefense research has been dubbed "the Persephone effect," referring to Demeter's daughter who was forced to spend six months every year with Pluto in Hell so she could live the other half of the year on Earth (Kwik et al. 2003).

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).

The security concerns about “dual use research” reflects a growing awareness that the rapid advances in knowledge and technology occurring in the life sciences that offer great potential benefits can by accident produce unexpected results or be misused to cause deliberate harm through bioterrorism or, even, biowarfare – for instance, that waged through “planned epidemics”. The life sciences tragically could become the death sciences.

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? And who should make these decisions and on the basis of what criteria? The difficulties in developing sound approaches for limiting the potential for misuse of research in the life sciences occur in part because virtually all the research that is aimed at protecting humankind from disease or otherwise improving the quality of life could theoretically be misused. 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 endeavour. “Enhancing public health and safety [and protecting public health] against biological threats arising from natural or man-made causes is an overwhelming challenge for traditional governance structures” (Taylor 2006). Laws and regulations would help to reduce the threat only if there were international accord and widespread concerted national legislation. 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.

Against the backdrop of this concern, the Fink Committee of the National Academy began to map out a strategy for responsible action within the scientific community—an effort that it hoped would spread worldwide. The Committee attempted to narrow 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 would either: (1) demonstrate how to render a vaccine ineffective; (2) confer resistance to therapeutically useful antibiotics or antiviral agents; (3) enhance the virulence of a pathogen or render a nonpathogen virulent; (4) increase transmissibility of a pathogen; (5) alter the host range of a pathogen; (6) enable the evasion of diagnostic/detection modalities; and/or (7) enable the weaponization of a biological agent or toxin. These classes of experiments of concern

focus 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 human behaviour biological modifiers, will need to be considered as well (Relman 2006). The development of synthetic biology has increased fears about such potential threats. And humans are not the only potential targets. Modification or destruction of plant and animal species could wipe out food supplies and have devastating ecological consequences.

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 Corson Report (National Research Council 1973) and embodied in National Security Presidential Directive 189 issued by President Reagan and post 9/11/2001 supported by 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" (White House 1985).

Classifying research findings places a legally binding barrier around the knowledge that is generated. Classifying knowledge in the life sciences means that high walls restricting the use of the knowledge generated can be established at the onset of research but not at a later stage. Research in the life sciences, unlike nuclear research, is not born classified and, in life sciences research, most "novel and unexpected findings" are made at a later stage. That means that most information of concern from life sciences research would fall into the area of "sensitive but unclassified," that is, information that might be dangerous, but that is not legally constrained. It is difficult to use the law to govern this situation, because of the unpredictability that is present as to when the law should be used to prohibit or restrict certain conduct and when not. To be valid law must be reasonably certain in its application, especially in the form of coercive or punitive legal measures,

Further, the United States does not have a monopoly on research in the life sciences that might be misused. RON is this sentence out of place now?

Thus, the means of constraint, if they are to be effective to protect scientific knowledge in the life sciences from misuse, might need to come from voluntary efforts within the global scientific community. This would require the development of a culture of ethical behaviour that takes into consideration national and global security. “Scientists are, in principle, no more or less responsible than any other citizen, but they are certainly expected to act responsibly by their public paymasters” (Campbell 2006). A self-policing approach leaves open the issue of enforceability, that is, how to ensure high levels of compliance and that compliance requirements are uniformly interpreted. The Fink Committee envisaged a living system overseen by a committee of scientists and members of the national security community, which would continually be charged with assessing 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 for the U.S. and as a model that could be extended internationally. “The NSABB is charged specifically with guiding the development of: A system of institutional and federal research review that allows for fulfilment of important research objectives while addressing national security concerns; 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). The NSABB has established a committee on “dual use” that is considering defining dual use research of concern for the life sciences as: (1) research with agents that possess a high biological threat potential; (2) research that could increase the potential of an agent to do harm; (3) research that could enhance the susceptibility of a host to harm; and/or (4) research in enabling technologies and facilitating information that may be misused to pose a biologic threat to public health and/or national security (Kasper 2005). The NSABB, as well as many international bodies, has also begun to

consider the role of ethics and responsible conduct in science to help protect against the misuse of the life sciences for biowarfare or bioterrorism.

Towards Professional Codes of Conduct

Recognizing that deplorable past breaches of ethics have occurred despite the presence of a code relevant to the conduct in question, also presents another challenge, namely guarding against the cynicism or despair the breaches may evoke in relation to the capacity of a code of ethics to have any or at least some worthwhile protective effect. But there is new reason for optimism in this respect. Research in the philosophy of science shows that as long as a small clustered nucleus of ethical voices remains, despite a majority of people acting only in self-interest, ethics has a high probability of reasserting itself; but if those voices are lost, so is ethics—at least from that source (Malinas and Bigelow 2004; Nowak et al. 1995; Somerville 2006a). Consequently ethics requires that we continue to try to be ethical ourselves, and to encourage and to help others to do likewise, even when - or especially when - we are in a minority.

In our view, there is an urgent need for an international consensus on the steps that must be taken to realize the goal of protecting against the misuse of science in the cause of bioterrorism or biowarfare. One such step is that throughout the world all persons and institutions associated with or involved in science or medicine – especially scientists, physicians, scientific institutions, international institutions (in particular, the World Health Organization), and others engaged in research and development in the life sciences—must be aware of their ethical obligations to prevent a horrific transformation of the life sciences to the death sciences. To promote such awareness we need to understand, in a very general way, what “doing ethics” requires; what is the role of people, whether ethicists or ethics committees, whose job it is to implement ethics in practice; and what instruments – for example, codes of ethics or laws – might help to ensure ethical behaviour. A code of ethics would help to set the normative standards for the behaviour we must strive to have implemented as one of the necessary, although not alone sufficient, protections against bioterrorism.

The international scientific community, in particular, has a key role to play in ensuring that efforts to manage the risks improve security and strengthen international collaboration to ensure non-maleficent use of scientific advances. The development of professional codes of conduct is of paramount importance for protecting science and the global public against the potential misuse of the life sciences. Adoption of a code of ethics to govern research in the life sciences is an important way to promote the necessary international consensus and to raise the necessary awareness to confront the dual use dilemma. Developing codes of conduct to help protect the life sciences from misuse for bioterrorism and biowarfare, thus, has become an important topic of discussion at many international scientific and governmental meetings. The Meeting of Experts of the States Parties to the BWC meeting in Geneva in June 2005, for example, considered the content, promulgation, and adoption of codes of conduct for scientists.

In constructing a code of ethics it needs to be recognized that language is not neutral and nowhere is the choice of language more important and difficult than in drafting provisions that can touch on some of our most profound and dearly-held moral values and beliefs. Codes of ethics unavoidably do that with the result that we may not always agree with each other about their provisions. But society cannot afford simply to walk away from a search for ethics in science because people cannot agree on what should or should not be included in a code of ethics. Rather, there is a need to establish a code and then use it as a basis to engage in an ongoing debate – that is, as a means to continue to foster “ethics talk” – because that is an important way in which ethics can move forward in conjunction with science as it advances (Somerville 2000). A code not only raises awareness of the need for ethics and provides some guidelines against which to judge the ethical acceptability of any given conduct, but also, functions as a teaching tool and provides less senior people, including students, with a means of raising ethical concerns, especially with respect to the conduct of those in authority. By actively supporting the creation and implementation of norms to govern the conduct of research and the communication of scientific information in the life sciences – including behavioural norms established through public discourse – national and global security can be enhanced.

The ancient Hippocratic Oath consists of particular provisions that apply in specific circumstances and, contrary to popular belief, does not explicitly articulate the mandatory injunction “first do no harm”. This is, however, the underlying general ethical principle on which all of the provision of the Oath are based and for which the Oath now stands. To reiterate its overall message: Physicians and Scientists must today, even more crucially than in the past, first do no harm – *primum non nocere*. And to paraphrase a provision in the modern Hippocratic Oath: Physicians and Scientists shall remember that they have a pact with society to advance knowledge and to apply that knowledge for the good of humanity. Scientists and scientific institutions must act responsibly to limit the potential misuse of scientific materials and information by potential bioweaponers. In particular, Revill and Dando (2006) see value for a Hippocratic-style oath for the life sciences as a means of helping to educate researchers about the dangers of dual-use research.

Basic Presumptions of a Code for Protecting the Life Sciences Against Misuse

Basic presumptions are the foundation stones from which we start an ethical analysis, or any other analysis or decision making. We cannot avoid such a starting point or the choice of what it will be. However, if we think about that reality at all, we usually take whatever basic presumption we use to ground our ethics analysis and decision making as a given, as self-evident. But, in fact, there is a choice to be made and that choice has a far from neutral effect on our ethical analysis and, consequently, a major impact on whether our decisions go one way or the other. Basic presumptions are important because they establish the decision making framework, including the ethical decision making framework, in which we ground our arguments.

There are four possible basic presumptions: “No”: we must not do this; “Yes”: we may do it, there are no restrictions or conditions on what we want to do; “No, unless...”: no, we must not do it, unless we can justify it and these are the requirements for justification; and “Yes, but...”: yes, we may do it, but not if certain circumstances prevail. Most ethical analysis involves situations where we must choose to use either a “no, unless” or a “yes, but” analysis. You might think that it doesn’t matter which of those we favour and that is

true where the ethical answer is relatively clear. But where we are equally doubtful about which of two courses of action to take, these two presumptions give polar opposite results. In such situations, a “no, unless” presumption means we may not proceed – a good example of this approach is the precautionary principle used in environmental ethics, which requires those creating risks to the environment to show that it is reasonably safe to do so before proceeding. In contrast, a “yes, but” presumption in the same circumstances means we may proceed until it becomes obvious that it is not reasonably safe to do so.

In democratic Western societies the basic presumption has been a “yes, but” one, including in relation to science. That is consistent with those societies having “open legal systems” – anything which is not prohibited is permitted – as compared with “closed legal systems” – anything which is not permitted is prohibited. The major exception to using an open legal system in Western societies is the regulation of pharmaceuticals and medical devices – since major tragedies in the early 1960’s, marketing and use is prohibited unless permission is given. One question now is whether certain science, for instance, that with serious “dual use” potential (the potential for beneficial use, but also for great harm, such as bioterrorism), should be subject to a similar approach. Once again, it will be difficult to find consensus.

Rappert (2004) points 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. A common theme of the discussions to develop a code for the life sciences is a principle we discussed previously, “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. The Interacademy Panel (IAP) recently 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 five 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; and 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.”

Elements of a Code to Counter Bioterrorism.

So what are the critical elements that a code of ethics for the life sciences should be based on, recognize and include. It needs to be built upon ethically relevant facts and articulate the substantive and procedural principles of ethics that must govern its interpretation and application in any given circumstances. Consequently, we propose these principles and provisions should include recognition that:

- The power of science to result in harm, if it is not governed by strong ethical standards, has been vastly augmented, in particular, by advances in molecular biology and informatics and especially in the context of the life sciences;

- Society has entrusted all people and institutions engaged in all aspects of science to undertake it in such a way as to show respect for life, in particular human life;
- Safeguards are needed to ensure fulfilment of the public trust and the fiduciary obligations it engenders, and to protect against breach, in particular, to ensure that science is not used in the cause of bioterrorism or biowarfare;
- Ethics must be embedded in all aspects of scientific research from its inception;
- The standards of behaviour embodied in a code of ethics will help to protect against the misuse of science, especially the life sciences;
- Compliance with a code of ethics and adherence to its principles is both the individual and collective responsibility of all people engaged in all aspects of science;
- A code of ethics will underline the importance of ethics reviews of proposed scientific research and the monitoring of on-going research, including by ensuring the ethics of involving humans or animals as research subjects;
- A code of ethics can establish a basic presumption of openness and transparency of scientific information and knowledge, but can allow for exceptions, the use of which must be justified by the persons relying on them to maintain secrecy, when there is a real risk such information or knowledge could be used to do serious harm;
- A code of ethics will support the protection of people who act in accordance with its requirements to bring breaches of ethics in scientific research or the misuse of science to the attention of relevant authorities or the public;
- Scientists, physicians, other researchers and scientific institutions who fail to act ethically are at high risk of losing the respect of their peers and the respect and the trust of society as a whole, which would have harmful consequences, not only, for them, but also, for scientific research, all people and institutions engaged in science, and society.

- Some breaches of ethics can concurrently constitute contravention of existing law and, because codes of conduct and ethical principles that are broadly accepted by one's peers are often used by courts to establish legal standards, violations of this code could result in legal penalties as well as censures for breaches of ethics;
- Persons with ethical or moral objections to participation in certain research need protection and support; and
- A code of conduct based upon strong ethical principles will facilitate transmitting the values that must govern scientific research to trainees and students and provide them with both guidance for themselves and benchmarks against which to assess the conduct of their teachers and mentors.

Proposed Codes of Ethics for the Life Sciences

There have been various proposals for a code of ethics or guidelines to govern the life sciences. As to be expected, these proposals have considerable overlap, which can be seen from the ones we include here. We have allowed this repetition in order to provide the reader with easy access to the contents of several proposals and to see which provisions are common to all of them and which are not.

Somerville and Atlas (2005) proposed a *Code of Ethics for the Life Sciences* as a way of engaging the scientific community and the broader public in a discussion of the actions needed for responsible conduct that could help protect against the potential catastrophic impacts of biological weapons. Given the potential harm that could be done to humanity by biological weapons we considered such responsible conduct by the scientific community essential and therefore proposed that the life sciences community had a mandatory obligation to follow the proposed code. As such, the code could well have implications since failure to abide by the code could be viewed as negligent or even reckless behaviour.

Under the proposed code, all persons and institutions engaged in any aspect of the life sciences would have to: "(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).

The NSABB has been working on developing a code of conduct for adoption by professional societies and for use by the U.S. government. The NSABB working group on codes of conduct has developed the following draft proposal. 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. Toward that end, according to the proposed NSABB code scientists should:

- Assess their own research efforts for dual use potential;
- Seek to stay informed of literature, guidance, and requirements related to dual use research;
- Train others to identify dual use research of concern and manage it appropriately;
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern; and
- Identify and report dual use research of concern through appropriate channels.

When designing and proposing research:

- Try to anticipate whether the end products of the research could be deliberately misused for harm;
- Design research that promotes scientific advances, while minimizing elements of dual use research that have potential for misuse;
- Consider the benefits of those dual use elements that cannot be avoided in light of the potential harm that might result from their misuse; and
- Modify the research design to manage and mitigate potential misuse.

When managing research programs in the public or private sectors:

- Promote awareness of dual use research issues and the accompanying responsibilities;
- Develop and maintain systems, policies, and training to ensure appropriate identification and management of dual use research; and

- Implement all guidelines and regulations specific to dual use research of concern.

When overseeing the research review process (e.g., funding agencies, institutional review committees, institutional leadership, etc.) :

- Ensure that all review systems are appropriately prepared to identify and manage dual use research concerns;
- Ensure researchers and reviewers are knowledgeable and compliant with all ethical, institutional, and legal requirements related to dual use research of concern; and
- Reconsider review systems periodically to ensure they reflect current knowledge and guidelines related to dual use research of concern.

When reviewing research:

- Stay informed about dual use research of concern and all applicable ethical, legal, and institutional requirements;
- Consistently assess proposals against the criteria for dual use research of concern during the review process; and
- Advise appropriate parties when the research under review meets the criteria for dual use research of concern.

When conducting research:

- Observe safe practices and ethical behaviors in the laboratory and ensure support personnel do the same;
- Use appropriate physical security measures and periodically reassess their adequacy;
- Observe applicable guidelines for the responsible conduct of dual use research of concern;

- Be attentive to the dual use potential of knowledge, products, and technology associated with all research activities; and
- Alert responsible institutional officials when dual use research of concern is identified and when decisions about its management are being made.

When collaborating on research activities:

- Discuss whether research knowledge, products, or technologies meet criteria for dual use research of concern and understand associated ethical responsibilities;
- Agree on specific individual responsibilities for the oversight of research with dual use potential;
- Respect expressions of concern that research efforts may have dual use potential and raise these concerns with appropriate oversight officials;
- Use appropriate measures to minimize risks to public health, agriculture, plants, animals, the environment, or materiel from research efforts; and
- Maintain a current awareness of national and international policies for dual use research of concern.

When communicating about knowledge, products, or technologies associated with dual use research of concern:

- Be aware of ethical and legal considerations in communicating about dual use research of concern;
- Weigh potential risks and benefits to public health, agriculture, plants, animals, the environment, or materiel that could result through research-related communications; and

- Consider options that may reduce or eliminate potential risks associated with research-related communications, while clearly identifying the benefits.

When providing oversight and training to new members of the life sciences community:

- Raise awareness about the meaning and importance of dual use research of concern;
- Inform developing scientists of ethical, legal, and institutional responsibilities associated with dual use research; and
- Encourage collegial discussion of dual use research issues, especially whether or not specific activities meet the criteria.

Yet another approach is to impose very strict standards on laboratories conducting research in the life sciences. In a very recent move “Biological research labs working with the most dangerous pathogens face stiffer city oversight under new rules approved by the board of the Boston Public Health Commission. Under the regulations, labs doing work at biosafety level 3 and 4 must obtain a permit from the commission, set up a safety committee that includes two outside community members and submit regular reports on research and safety procedures. In addition, Boston labs can't try to create weapons or conduct classified research and must hold public meetings to disclose research being done. Labs that fail to comply with the new rules could face fines of \$1,000 per day, per violation and a suspension of their research” (Associated Press 2006).

Regardless of which approach or code is adopted and/or whether a code is viewed as mandatory (the code must be followed) or voluntary (scientists should follow the code), 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. Inevitably there will be an important interface between any professional code of conduct and codified laws and regulations. Whistleblowing, that is, exposing potential harms to authorities and/or the public is an important ethical responsibility. 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. Also, as evidenced in the Thomas Butler case (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 diseases. Peer pressure within the scientific community needed to ensure full compliance with antiterrorism laws and biosafety/biosecurity regulations, which are viewed by many as excessively restrictive and impeding legitimate science, and the establishment of a code of conduct to reduce the threat of the misuse of the life sciences have yet to be achieved. Further efforts to establish a culture of responsibility are needed to ensure fulfilment 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.

Responses to Proposed Professional Codes of Ethics.

The proposal for professional codes of ethics and the contents of the code proposed by Somerville and Atlas have both met with strongly conflicting views. Van Aken (2006) doubts that any system based solely on responsibility and self-regulation will be sufficiently comprehensive and effective. According to Van Aken (2006) “first and foremost, any such system must be able to cast legally binding verdicts, even if scientists favour non-binding systems based on their own individual or collective responsibility. He proposes that an international standard setting body should be responsible for defining experiments of concern and for reviewing those that are most critical. This is also the view of Steinbruner and colleagues (Steinbruner and Okutani 2004). They propose that certain lines of scientific enquiry should be prevented and that there should be an international body empowered to make such legally binding determinations. Similarly, Corneliussen (2006) questions the value of self-regulatory codes of conduct unless they are accompanied by other measures, including mandated regulatory measures that are backed by sanctions and real threats of serious penalties.

The scientific community increasingly recognizes that science itself is not a value-free activity and, therefore, the choice of what research to undertake and how to undertake it must be governed by ethical principles. But there is still a nucleus of scientists who oppose that concept, arguing that there must be no restrictions on the search for new knowledge, and that ethical principles only become relevant in the application of that knowledge. Scientists' reasons for holding such a view can range from cognitive (ethics requirements won't work), to emotional (fear that they will shut down science), philosophical (science is value free, it's only its applications that need ethical guidance), misguided (scientists are ethical people and all that ethics requires is that they act in good conscience), monetary (the ethics requirements will bankrupt our company) and personal (they will ruin my career).

Letters sent to *Science* in response to the publication of the code of ethics to govern the life sciences that we proposed (Somerville and Atlas 2005) attested that the code had caused people to think about the value of ethics and the need to act to protect science from misuse. These letters enriched the original discussion and opened up further major issues. The majority confirmed the view that codes are valuable and that "ethics talk" involving the broadest possible range of participants is even more valuable.

Matters that were raised included that the values and ethical standards enshrined in a code of ethics must be reflective of a very broad spectrum of people that stretches well beyond those of a given profession and that the public must have a strong voice in deciding on these values and ethical standards. Ethics requires more than scientists just acting in good personal conscience, and the same is true of them acting collectively as a profession in good professional conscience. Rather, the broadest possible range of people and institutions must be involved in ethics decision making in relation to science for that decision making to be ethically acceptable.

Some of the ways in which we can engage people outside science and, in particular, the public, in setting values and ethical standards for the life sciences include the following:

- Ethics review of all research, as is now the norm, must be undertaken by ethics committees that have a very broad-based membership.
- Recognizing that the scientific professions hold science on trust for society, establishes that society has the final say as to what will and will not be allowed in terms of ethics.
- Adopting a basic presumption of openness and transparency of scientific knowledge and information allows the public to monitor the ethics of science on an ongoing basis, as does the protection of “whistle blowers”.
- An express duty to bring to the attention of the public or appropriate authorities activities that are unethical or could contribute to bioterrorism or biowarfare engages public participation in decision making about these activities.
- Likewise, requiring protection and support for persons with ethical or moral objections to participation in certain research, and protecting their freedom of conscience, promotes public knowledge and involvement in the ethics of science.
- And, we must encourage an on-going debate about contested values and beliefs, as a means of stimulating “ethics talk”, an important way in which ethics is developed and implemented in practice. It is widely accepted in ethics that this “talk” must include the public and it merits stating that the “ethics talk” we need must go beyond any one country to include broad international participation.

More specifically, as indicated above, providing protection for “whistleblowing” is an essential element in implementing ethics in science. Sometimes difficulties can arise because the person or body to whom one would normally report has a conflict of interest. For example, one’s own government could (and would, unless procedures were put in place to avoid it) have a conflict of interest in receiving information about its own wrongdoing. In such cases, it would not be an appropriate authority to which to report. Who would be the appropriate authority must be determined on a case-by-case basis and

might include a role for other national authorities or international ones, as well as the public.

We do not need to reinvent the ethical wheel. For instance, medicine has considerable experience in developing ethical guidance in relation to both research and practice and we should use these developments as models. It is important to identify and build on all presently existing relevant resources. And those resources may also benefit from comparison with others. Moreover, ongoing monitoring of ethics as the research evolves is not only instructive ethically, but also, is required as part of “doing ethics”.

Even those who question the value of a code agree that research in the life sciences, including biodefense research, must be conducted in a safe and ethical manner. Such assurance is essential to maintain the public trust, which, in turn, is essential for the continued support of research. Bodies speaking out publicly about this need for ethics include, the General Assembly of the World Medical Association in adopting the *Washington Declaration on Biological Weapons* (World Medical Association 2002), the British Medical Association (British Medical Association 1999), the US National Research Council (National Research Council 2004), the British Parliament (House of commons 2003), and the Asia-Pacific Economic Cooperation (APEC) Leaders (APEC 2003), among others (Rappert 2006). Most recently in October 2006, the World Health Organization convened a working group consultation in Geneva on research and development in the life sciences, public health and global security. Many of the ethics issues we discuss in this chapter were also raised in that context.

Concluding Remarks

One way to raise the awareness of people in the life sciences to their ethical obligations is through national and international adoption of a code of ethics to govern research in the life sciences. Experience has shown that professional specificity of ethical requirements is needed for scientists to personally identify with them and, as a result, apply them in practice. Consequently we need statements about ethics and ethics research specific to the life sciences.

Then, it's not enough to have ethics on paper; ethics must be implemented in practice. An important example of the practical operationalization of a code of ethics is seen in Europe as a consequence of steps taken by the European Commission. We can learn much from the European experiential ethics knowledge that has resulted.

It needs to be recognized that a code of ethics alone is not a complete solution – that some, possibly even many, people will not comply with the code. But to ask whether a code will provide complete protection is the wrong question. The right question is whether society is better off with a code than without one. The argument we put forward (Somerville and Atlas 2005) is that society is better off with one.

Whatever steps we take to implement ethics we will not instantiate a perfect system, but the right question is not whether we can find a perfect system, but whether we are better off with than without any measures that might be implemented to promote ethics. Critics of the formal implementation of ethics believe for instance that “imposing ethical standards ...will demonize the scientific community”; that scientists will not inadvertently “develop weapons through their benign research efforts”; and that “aggressive law enforcement and intelligence efforts” are the only ways to counter bioterrorism and are not complemented by implementing ethics (Perman 2005). It can be argued that such views are counter-productive in terms of ensuring ethical science and must be challenged. Ethics is integral to science, which means that unethical science is bad science, not just bad ethics. Like all elements of good science, ethics must be intentionally included. Scientists need support to fulfil their ethical responsibilities to help protect against the misuse of science by those who would do harm.

The basis on which societal-level trust is established has shifted in post-modern Western societies from *blind trust* – “trust me to make all the decisions, because I have knowledge, power and status that you don't have, and I know what is best for you and will act in your best interests” to *earned trust* – “trust me because I will show that you can trust me and thereby earn your trust” (Katz 1984). Earning trust requires openness, honesty and integrity. It is a continuing process not an event and, in particular, requires the sharing of information and the informed consent of those who give their trust. All of

which means that the public has a critical role in deciding on the ethics that should govern the life sciences and that structures must be put in place to ensure and to show the public those ethics are consistently applied by scientists in practice. Dialogue and “ethics talk” with constituencies within and beyond the scientific community are critical to achieving that goal. Scientists must develop a manifest culture of responsibility to maintain the public trust upon which not only science, but also public safety and public health now depends.

Finally, life sciences research promises great benefits from new knowledge and technologies but also it creates the potential risks for public health. We must avoid being hysterical or fear-mongering, but we would be very remiss to underestimate the harm that could be unleashed. Let’s hope that with coordinated, international, sustained efforts we can ensure a future in which everyone can feel that ethics prevails, that public health is protected and, as a result, the fear of an “accidental, negligently caused or planned epidemic” can be realistically reduced to a minimum (Somerville 2006b).

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