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Commentary

Bioterrorism and the Responsible Conduct of Biomedical Research

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ABSTRACT This article discusses the ethical responsibilities of biomedical researchers to prevent bioterrorism, including duties related to research, publication, editorial review, public education, expert opinion, advocacy, and reporting suspicious activity. Since actions taken to avert bioterrorism may also undermine important scientific norms, such as openness, freedom, and collegiality, and individual rights, such as privacy, biomedical scientists may encounter ethical dilemmas and problems when they consider taking steps against terrorism. This article proposes some policies and recommendations that attempt to strike a fair and reasonable balance between protecting scientific norms and individual rights and promoting national and international security. This article articulates policies and recommendations that will help ensure that the norms that govern biomedical research and individual rights are not casualties in the struggle against terrorism. Drug Dev Res 63:121–133, 2005.

Key words: bioterrorism; openness; research; ethics

INTRODUCTION

Responding to the threat of terrorism is one of the greatest moral and political challenges that civilized nations face today [Stern, 2000].[1] Terrorist groups have used or are planning to use chemical, biological, and nuclear weapons to inflict massive destruction on military and civilian targets across the world [National Research Council (NRC), 2002, 2003]. They have also damaged or are planning to damage transportation systems, communication systems, financial systems, water and sewer systems,

[1]Defining the words ''terrorist'' and ''terrorism'' is an important part of an appropriate response to the problem of terrorism. Although some world leaders, such as President Bush, often speak of a ''war against terrorism,'' this phrase is conceptually inaccurate. The American Heritage Dictionary [2000] defines terrorism as the ''unlawful use or threatened use of force or violence by a person or an organized group against people or property with the intention of intimidating or coercing societies or governments, often for ideological or political reasons.'' Black's Law Dictionary [1999] defines Terrorism as the ''use of or threat of violence to intimidate or causes panic, especially as means of affecting political conduct.'' According to these definitions, terrorism is a strategy, which may be used by individuals or groups. Since terrorism is a strategy, not a government or group, there can no more be a war on terrorism than there can be a war on torture. However, there can be a systematic response to individuals or groups, i.e., terrorists or terrorist groups, which use terrorism as a strategy. This article will focus on the problem of how scientists can respond to individuals or groups that use

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energy networks, and other economically significant elements of the social infrastructure. Negotiation and deterrence, two of the most effective strategies for avoiding warfare among nations, have little effect on terrorists, since many leaders of these groups espouse a philosophy of martyrdom, violence, and apocalyptic confrontation with the enemy. Most terrorist groups use terrorism as a strategy for achieving religious or ideological goals [Stern, 2000].

Shortly after the hijackings of September 11, 2001, which killed more than 4,000 people, someone mailed letters containing anthrax spores to dozens of people in the eastern United States, killing four people and sickening more than twenty. The anthrax attacks caused a great deal of fear and anxiety, and thousands of people began taking antibiotics as a prophylactic measure [Resnik and De Ville, 2002]. Since the person who committed these acts of terror has not been captured or identified, law enforcement and intelligence authorities continue to work on this case. Terrorist organizations have declared that they are interested in acquiring weapons of mass destruction (WMDs), such as biological weapons, and using them on civilian populations. A Japanese terrorist cult known as Aum Shinrikyo released sarin gas in a Tokyo subway on March 20, 1995. The attack killed 12 people and injured more than 5,500.

To combat terrorism, many nations have adopted new rules to prevent terrorists from acquiring WMDs [American Association of University Professors (AAUP), 2003]. The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) [2001] makes it a crime to possess or transfer a biological agent, toxin, or delivery system in a quantity that would not be reasonably used for a peaceful purpose. The Patriot Act includes a listing of select biological and chemical agents, i.e., pathogens and toxic compounds, and bars restricted persons from having access to these agents. The Public Health Security and Bioterrorism Preparedness and Response Act [2002] requires institutions that possess select agents to develop an inventory of these agents and to take steps to improve security.[2]

From 2001–2002, several reports were published in scientific journals that could help terrorists develop biological weapons. These included a paper on how to increase the virulence of a mousepox virus, published in the *Journal of Virology* [Jackson et al., 2001]; a paper that demonstrated how to overcome the human immune system's defense against smallpox, published in the *Proceedings of the National Academy of Sciences* [Rosengard et al., 2002]; and a paper on how to make a poliovirus through ordering DNA by mail from a private company, published in the journal *Science* [Cello et al., 2002]. Several members of the U.S. Congress introduced a resolution criticizing the publication of these papers, and other politicians called for censorship of scientific journals.

In January 2003, the American Society for Microbiology (ASM) and the National Academy of Sciences (NAS) held a meeting to discuss the control of biological information that poses security risks. The ASM developed a policy for reviewing articles that raise security risks. Many scientific journals, including *Science* and *Nature*, also initiated a policy of giving special scrutiny to papers that pose security concerns [Malakoff, 2003; Journal Editors and Authors Group, 2003].

These and other events following September 2001, prompted the NRC to study national and international security issues related to biotechnology. In 2003, the NRC issued a report addressing the relationship between biotechnology research and bioterrorism. The report made seven recommendations for steps that governments and scientists should take to prevent bioterrorism, including development of criteria for reviewing experiments of concern prior to publication and at publication, creation of a national advisory board for biodefense, periodic review of policies to protect biological materials from misuse, as well as education for scientists concerning their ethical

terrorism. One reason why groups use terrorism to achieve their goals is that they lack the power or resources to combat their enemies by conventional means. Terrorism is a tool that a weaker adversary can use against a stronger one.

[2]It is beyond the scope of this paper to discuss the full range of policy options that could increase or decrease the threat of terrorism. Since national security threats could be manipulated or exaggerated for domestic political gains, it is important for any effective policy to be based on an honest and objective assessment of the available information. It is also beyond the scope of this paper to compare the threat of bioterrorism to other threats related to terrorism, such as nuclear terrorism, or to engage in a debate about how best to use public resources to combat terrorism. If terrorists are able to obtain a nuclear weapon or damage a nuclear power plant, the results could be catastrophic. From our perspective, it does not matter if bioterrorism is less of a threat than nuclear terrorism. All that matters is that it is a serious threat, which requires urgent and concerted action.

responsibilities to mitigate the risks of biotechnology [NRC, 2003].

In this article, we argue that biomedical scientists have ethical obligations to help prevent bioterrorism, including duties related to research, publication, editorial review, public education, expert opinion, advocacy, and reporting suspicious activity. The duty to help prevent terrorism, while important, is not an absolute or overriding obligation. Sometimes the duty to help prevent bioterrorism may also conflict with scientific norms, such as openness, freedom, and collegiality, and individual rights, such as privacy. When this occurs, biomedical scientists may encounter ethical dilemmas and problems as they attempt to balance their obligation to help prevent terrorism against other obligations and duties. Our article will articulate policies and recommendations, which will help to reduce the risk that the norms that govern biomedical research and individual rights become casualties in the struggle against terrorism.

THE RESPONSIBLE CONDUCT OF RESEARCH

The Responsible Conduct of Research Scientists have many different ethical responsibilities in their roles as researchers, educators, experts, advocates, and concerned citizens. These responsibilities are based on their obligations to colleagues, clients, students, organizations, and the public at large. Many of these ethical duties arise from scientists' relationships with other people within the research community, such as norms related to experimental design, reporting of research results, research integrity, data management, data sharing, data analysis, conflict of interest, authorship, mentoring, and peer review [Shamoo and Resnik, 2003; Macrina, 2000]. Other norms are based on scientists' relationships with society at large, such as norms related to human research, animal research, obedience to the law, intellectual property, freedom of inquiry, expert testimony, communicating with the media, public education, and social responsibility [Shamoo and Resnik, 2003; Shrader-Frechette 1994]. The ethical codes and guidelines adopted by scientific associations, journals, universities, and government agencies recognize and reinforce these norms [NAS, 2002].

Social responsibility is one of the most important ethical norms in science. Scientists, both collectively and individually, have a responsibility to benefit society: scientific research should be conducted not only to gain knowledge but also to improve the human condition [Resnik, 1998; Kitcher, 2001]. A great deal of biomedical research benefits society by promoting the development of new medications, therapies, and crops. Since research has positive and negative consequences in the short-term and long-run, and it is often very difficult to anticipate these outcomes, it is not realistic to expect scientists never to conduct research that causes any harm to anyone or anything. However, scientists should strive to conduct research that they reasonably believe will result in a net benefit for society, and they should avoid conducting research that they have good reasons to believe would produce more harm than good for society. Since most research will have beneficial and harmful uses, it will sometimes be difficult to decide whether a project will have a net benefit for society. We realize that most research has a dual use and that making the determination of net benefits is very difficult.

Most codes for ethical conduct in science support a collective and individual duty of social responsibility. The codes acknowledge that scientific professions have obligations to society as well as to individual scientists. According to the ASM Code of Ethics, "ASM members aspire to use their knowledge and skills for the advancement of human welfare" [ASM, 2000]. The Chemist's Code of Conduct, adopted by the American Chemical Society (ACS), states that, "Chemists have a professional responsibility to serve the public interest and welfare and to further knowledge of science" [ACS, 1994]. The Code of Ethics of the American Society of Biochemistry and Molecular Biology (ASBMB) contains a lengthy statement about social responsibility: "In fulfilling OBLIGATIONS TO THE PUBLIC, it is EXPECTED that: investigators will promote and follow practices that enhance the public interest or well-being; investigators will use funds appropriately in the pursuit of their research; investigators will follow government and institutional requirements regulating research such as those ensuring the welfare of human subjects, the comfort and humane treatment of animal subjects, and the protection of the environment; investigators will report research findings resulting from public funding in a full, open, and timely fashion to the scientific community; and investigators will share unique propagative materials developed through publicly-funded research with other scientists in a reasonable fashion." [ASBMB, 1998].

There are at least two reasons why scientists and scientific organizations have obligations to the benefit of society. First, most scientists receive public funding or have benefited from public funding. In the United States, the federal government spends more than $125 billion per year on research and development, and state governments allocate billions of dollars each year toward educational institutions [Shamoo and Resnik, 2003]. Scientists have an obligation to provide society with a return on its investments of money and resources. Social responsibility is part of science's "contract" with society. Second, scientists, like other members of society, have moral duties of beneficence and harm prevention/avoidance [Beauchamp and Childress, 2001]. Since scientific research can cause considerable good (or harm) for society, scientists have a moral obligation to promote beneficial consequences of their research and to prevent or minimize harmful ones.

PREVENTING BIOTERRORISM AND THE PROLIFERATION OF BIOWEAPONS

There are many different strategies for preventing terrorism, such as spying on terrorists; apprehending terrorists; punishing terrorists; negotiating with terrorists; developing or changing laws or policies; addressing the social, political, and cultural causes of terrorism; and preventing terrorists from acquiring the means to commit violence. Preventing terrorists from acquiring WMDs is one of the methods for preventing acts of terror. To prevent terrorists from acquiring WMDs, countries must exert some control over these weapons. There are three basic means of controlling the proliferation of WMDs: (1) controlling materials used to make WMDs, such as plutonium or enriched uranium; (2) controlling information used to make and develop WMDs, such as information about the design of nuclear weapons, and (3) controlling the people who have knowledge, expertise, and skill to make WMDs, such as nuclear scientists [NRC, 2003] and microbiologists [NRC, 2003].

These methods of controlling weapons proliferation are not equally effective against all types of weapons. For example, controlling the materials used to make nuclear weapons has proven to be a very effective method for controlling the spread of nuclear weapons, since the materials used to make nuclear weapons are very difficult to obtain or manufacture and are relatively easy to detect [NRC, 2003]. Controlling the materials used to make biological weapons has proven to be not as effective at controlling the proliferation of biological weapons, since the materials are easier to obtain and can be much harder to detect. Anthrax, for example, occurs in the wild. If a terrorist is unable to obtain anthrax from a laboratory, he or she could collect it from decaying animal carcasses. A terrorist could also mutate commonly available microbes, such as the bacteria that cause pneumonia.

Controlling the information used to make WMDs can be very difficult [NRC, 2003]. Although information about how to make atomic bombs was once highly classified, one can now find designs for nuclear weapons on many different Internet sites. While the knowledge of how to weaponize microbes, such as anthrax, is not being distributed over the Internet or other highly public media outlets, most scientists trained in biochemistry or microbiology would know how to convert microbe substrates into aerosols or powders that could be delivered by air. Much of the publicly available basic knowledge in genetics, genomics, microbiology, and biotechnology could help terrorists to develop bioweapons. Although it is important to try to prevent terrorists from gaining any new knowledge that could help them develop bioweapons, a great deal of basic biochemical knowledge related to bioweapons is now, and should be, in the public domain. Biomedical science could not move forward without these basic research results.

Controlling the people who know how to make WMDs is not as difficult as controlling the information used to make WMDs, since it often takes years of undergraduate and graduate education and training to develop the expertise needed to make a highly effective nuclear, chemical, or biological weapon [NRC, 2003]. Making an effective WMD is not as easy as making a bomb out of two tons of fertilizer or hijacking a commercial airplane. People with the knowledge and expertise to make WMDs will usually be fairly easy to detect, since they will have attended colleges and/or universities. For example, after the collapse of the Soviet Union, the United States and Russia worked together to find employment for scientists who worked on WMDs so they would not be tempted to sell their skills to terrorists. Unfortunately, it is likely that terrorist organizations have already attempted to contact scientists from the former Soviet Union who worked on biological weapons, Many of the members of the Aum Shinrykio cult had doctoral degrees in science. It is very likely that the person responsible for the anthrax attacks in the fall of 2001 had graduate training in biotechnology or microbiology [NRC, 2003].

Controlling people is a difficult, but not impossible task. There are several ways of "controlling" people, including education, mentoring, surveillance and monitoring, legislation, and law enforcement. Later on, this report will discuss different ways of controlling people to prevent bioterrorism, including reporting suspicious activities and education. The main difficulty with controlling people is reconciling state control or influence over biomedical scientists with freedom and privacy. Obviously, it is much easier for a totalitarian regime to exert control over its scientists than it is for a democratic state. Democratic societies must find a way of controlling the conduct of biomedical scientists without undermining freedom and privacy.

Another difficulty with controlling scientists is that scientists frequently move across borders. For example, many scientists from foreign countries complete their graduate education in the United States and then return to their own country or another one. The United States has very little ability to exert control over people living outside its borders. To deal with this problem, countries (and scientists) that are opposed to bioterrorism must cooperate to develop international agreements, policies, and procedures. For example, if the United States is concerned about a scientist who has studied in the United States but is now living in another country, then it should be able to work with that country to determine whether that scientist poses a security threat.

BIOTERRORISM AND SOCIAL RESPONSIBILITY

This article will now discuss how social responsibility applies to the methods for preventing bioterrorism, discussed above. Since all scientists have an obligation to prevent harm to society, and acts of terrorism can cause substantial harm to society, all scientists have an obligation to help prevent terrorism.[3] This obligation is not absolute, however, and it may conflict with other obligations or duties. For example, the obligation to help prevent terrorism may conflict with obligations to share data and disseminate knowledge. When such conflicts arise, scientists must decide how to balance these different obligations. We address some of the conflicts that arise in preventing terrorism below.

Scientists also have special obligations related to their area of expertise. For example, computer scientists have an obligation to prevent cyber terrorism, nuclear scientists have a special obligation to prevent acts of nuclear terrorism, and biomedical scientists have a special obligation to prevent acts of bioterrorism. Biomedical scientists can honor their responsibilities to prevent bioterrorism by refraining from activities that are likely to aid bioterrorists and by engaging in activities that are likely to counteract or thwart bioterrorists. Social responsibility for biomedical scientists is especially important given proposed legislation to identify, understand, and respond to biological agents of terror [Heil, 2003; Turner, 2004; Fiorill, 2004]. We will now discuss some of the specific responsibilities of biomedical scientists related to bioterrorism prevention.

The Duty Not to Conduct Research That Is Harmful or Dangerous to Others

Sometimes the freedom to conduct research, which is such an essential part of the ethos of science, conflicts with social responsibility. Freedom, even the freedom of inquiry, is not absolute. One's freedom can be restricted to prevent harm to other people. To decide whether and how to restrict an individual's freedom, one must consider the probability, magnitude, preventability, and immediacy of the harm that his or her conduct could may cause to others [Feinberg, 1984]. The restriction on one's freedom to cause harm to others also implies a duty not to cause harm to others. Thus, one should not conduct research if the research is likely to cause substantially more harm than good. The right to seek and disseminate knowledge can give way to other moral obligations, such as the duty to not harm other people [Kitcher, 2001].

Applying these ideas to bioterrorism, one could argue that biomedical scientists should not conduct research that is likely to produce substantially more harm than good, including research that could help terrorists develop bioweapons. Few people would challenge this assertion as a general statement of principle. Applying it to particular cases, however, can pose difficult ethical challenges. It is rarely the case that a research project produces only harmful results or only good ones. The results of most biomedical research can be used for beneficial or harmful purposes. Research results that can help terrorists develop new weapons can also help scientists develop new methods for treating disease or preventing bioterrorism. For example, terrorists could use the results from the study on how to overcome the human immune system's defenses against smallpox to develop a more virulent form of this virus, if they can acquire any of the smallpox virus. Biomedical researchers could use the results of this study to develop better therapies designed to prevent or treat the smallpox virus, including any strains of the virus engineered by terrorists to overcome the human immune system's defenses. Even basic research in biomedicine can be

[3]We are assuming, of course, that acts of bioterrorism would cause great harm. Someone who supports the political aims that terrorists are attempting to achieve might challenge this assumption on the grounds that bioterrorism is a strategy that can be justified as a means of obtaining those aims. Indeed, one might argue, following the example of the scientists that worked on the Manhattan Project, that scientists have a social responsibility to help terrorists acquire weapons of mass destruction. If Robert Oppenheimer was honoring his civic duty by leading the team of scientists that developed an atomic bomb, then another scientist could fulfill his social responsibility by helping terrorists develop bioweapons. We do not have time to fully address these objections to our assumptions that bioterrorism would be a great harm to society, but we would at least like to point them out. A more in-depth discussion of these issues would have to address such questions as, ''which society should scientists benefit?'' ''is violence ever justified to achieve political means?'' and ''should scientists help develop tools and techniques used to perform acts of violence, prevent acts of violence, or defend a country against violence?''

used for good or evil. For instance, one could use information about human genetic variation to develop drugs tailored to treat people with specific genetic predispositions, or one could use the same information to develop weapons that target people with specific genetic vulnerabilities. Given the high degree of racial and ethnic animosity and strife in the world, researchers should take special precautions to avoid engaging in research that could be utilized to develop pathogens that afflict only particular racial or ethnic groups.

Because a great deal of research in biomedicine has a dual use—for social benefit or for terror—it can sometimes be very difficult to know whether one should refrain from conducting a particular research study, not conduct the study at all, or conduct the study but keep it secret [NRC, 2003]. Given the dual use conundrum in biomedicine, scientists should carefully assess their proposed projects and attempt to anticipate how they will be used by other scientists, clinicians, patients, and, potentially, terrorists. If the potential harms of a research project are likely to substantially outweigh the potential benefits of the project, then researchers should consider taking steps to prevent potential harms from occurring, such as abstaining from the project, conducting the project in secret, or undertaking the project but not disseminating the results widely.

The Duty to Not Publish Dangerous Research

For a variety of social, ethical, and political reasons, it will rarely be the case that scientists will decide to abstain from conducting research that they believe has some scientific or social value. Given the importance of freedom of inquiry and the force of scientific curiosity, most research projects that can obtain funding will go forward in some fashion or other. The right to publish, important though it may be, is weaker than the right to inquire (or speak or think). The reason that the right to publish is weaker than the right to inquire is that publication is an act of disseminating information to the public at large, whereas inquiry may affect only a few individuals. Because publication has a wider audience than inquiry, publication can create much greater harms to individuals and society than inquiry. For this reason, the United States and other countries have laws forbidding or restricting forms of publication that can cause harm, such as libel, copyright infringement, or child pornography [see Feinberg, 1984; Barron and Dienes, 1999].

Thus, when confronted with potentially dangerous topics of inquiry, scientists (and their benefactors) will usually decide to go forward with the research but control the dissemination of information. This strategy allows scientists to seek knowledge while attempting to prevent the harmful use of that knowledge. Thus, most of the ethical questions about avoiding the negative consequences of a research project will focus on the means used to control access to its results. Should the project be classified? Should it be published? Should only parts of the project be published? Should the project be published in a widely read journal or only disseminated to a small audience? These are the questions researchers and research institutions must face once they have decided to conduct potentially harmful research while attempting to minimize its adverse effects.

The NRC [2003] recently identified seven types of studies that are potentially dangerous and require additional review to determine whether (or how) they should be published. These include studies that would: "(1) Demonstrate how to render a vaccine ineffective. (2) Confer resistance to therapeutically useful antibiotics. (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. (7) Enable the weaponization of a biological agent or toxin" [NRC, 2003, p. 5]. While it is useful to develop a list of types of studies that require additional review, many studies that belong to one of these seven types may not be especially dangerous, and many studies that are not mentioned on this list could be very dangerous.[4] Researchers should make decisions about whether to publish potentially dangerous research by carefully examining the facts in each case and weighing benefits and risks to science and society. Since many different studies in biology have beneficial and harmful uses, it may be very difficult in some cases to decide how to balance the benefits and risks of publication [NRC, 2003].

Ideally, researchers, not government agencies, should make decisions about whether to publish potentially dangerous research, since entrusting government agencies with such decisions can lead to censorship of research for political purposes [Atlas, 2002], Although government agencies may offer valuable input into publication decisions, it is important to avoid government censorship of research that has not already been classified. If the government has not already made the decision to classify a research project, then it should be the type of information that is normally shared freely among scientists. Scientists should therefore decide whether and how to share

[4]For example, a study that would identify strategies for contaminating the water supply with biological agents would be a very dangerous type of study that is not included on this list. A study on a how to infect laboratory mice with rhinoviruses would not be especially dangerous, but it would be on the list.

this information, since additional oversight by the government can have a detrimental impact on scientific freedom and openness [AAUP, 2003]. Additionally, in the United States, content-based restrictions on the sharing of information may constitute unconstitutional violations of free speech, if those restrictions are not the least burdensome method of meeting a compelling government interest [Robertson, 1977]. Thus, government censorship of potentially dangerous research, conducted in a non-classified setting, could be illegal in the United States.

Although the government should not act as a censor of unclassified research, it should provide scientists with expertise and advice concerning the publication of research that poses high-security risks. Scientists who make decisions about publishing research, such as journal editors, could consult a special committee, established by the government, on an ad hoc basis. The committee would be composed of individuals with expertise in the relevant scientific, legal, and humanistic disciplines and could make recommendations concerning publication and dissemination. It would be very important to have representatives on the committee who have some knowledge concerning terrorist activities and methods, such as sociologists, journalists, political scientists, or military officials. To avoid censorship, the committee's recommendations would be advisory, not mandatory. Journal editors would consult the committee prior to publication of research that represents a high-security risk. In some cases, the best strategy for publication may be to disseminate the results of a dangerous project to a small community of researchers through special seminars or limited publications. This strategy would help to advance science by allowing the research results to circulate within a small community of experts, and it would avoid some of the problems of disseminating the results to the public at large.

If a project is too dangerous to publish, it could be conducted as classified research or protected under trade secrecy laws [NRC, 2003].[5] In the United States, classified research is disseminated only to people who have the appropriate clearance and a need to know the results of the research. The decision to classify research allows the science to go forward while keeping it out of the hands of terrorists. At some point in the future, the government could make a decision to declassify the research and make it available to the public. If the dangerous research is sponsored by a private company, and has not been classified, then the company could use its trade secrecy rights to prevent the research from being disseminated publicly.

The Duty to Maintain the Confidentiality of Classified Research

If the government has classified a research project, then scientists working on that project have an ethical (and legal) obligation to keep the research confidential, even if the research does not appear to be especially dangerous. The reasons for maintaining confidentiality are straightforward: scientists should not disclose classified information because such disclosures can undermine national or international security, and violate promises made to the government to maintain secrecy [Resnik, 1998].

Scientists have occasionally violated rules concerning classified research because they have believed that social responsibility required them to divulge these secrets. For instance, there is some evidence that U.S. scientists shared classified atomic research with the Soviet Union after the atomic bomb was developed so the two sides could avoid war through nuclear parity [Beth et al., 1995]. More recently, Israel convicted Mordechai Vanunu of treason for disclosing classified information about its secret nuclear weapons program. Vanunu has been thrice nominated for the Nobel Peace Prize for providing the world with information about Israel's nuclear weapons programs [Day, 1992]. Even if social responsibility sometimes requires scientists to violate rules concerning classified research, it is highly unlikely that society would benefit from such disclosures in the case of research aimed at preventing bioterrorism, since terrorists could use this information to defeat these preventative strategies. Violations of classification rules would probably promote rather than prevent bioterrorism.

One of the main drawbacks of restrictions on the dissemination of research results is that secrecy can be

[5]Under U.S. laws, classified research is research with military or strategic value, usually sponsored by the government. The government makes a decision whether research should be classified when it decides to sponsor the research. The government also has the authority to co-opt private research and declare it to be classified or refuse to grant a patent for an invention that constitutes a threat to national security. All nuclear weapons research is "born classified," which means that the government will classify any research, public or private, deemed to have relevance for nuclear weapons. A policy adopted by the United States in 1985 holds that the government will not place any restrictions on fundamental research, which is defined as research that is ordinarily shared broadly within the scientific community. If research is sponsored by the government and is not classified, then scientists are required to make their results available to the public. Indeed, the Freedom of Information Act allows individuals to gain access to government sponsored, non-proprietary research that has is not classified or is not protected by medical privacy laws. Even when the government lacks the authority to declare research to be classified, scientists are free to petition the government for classification [NRC, 2003].

used to cover up illegal, unethical, or incompetent science. The decision to restrict access to research should not be manipulated to avoid discovery of misconduct, financial mismanagement, or human rights abuses. In general, good science requires an open environment, subject to outside criticism and debate. In recognition of this point, we hold that decisions concerning the dissemination of scientific information, including decisions concerning classification, should be made with as much internal and external input as is feasible, by people with different disciplinary backgrounds, subject to independent review from disinterested parties. It should always be possible to investigate illegal, unethical, or incompetent research [Turner, 2004].

The Duty to Not Share Dangerous Biological Materials

As noted earlier, the Patriot Act bars restricted persons from having access to select biological agents. Other laws also require research institutions to account for their inventory of these select agents, to conduct background checks on personnel who request access to select agents, and to keep track of who has access to select agents [Gaudioso and Salerno, 2004]. All of these rules are designed to prevent terrorists from acquiring biological materials that they could use to make weapons. Since preventing access to the materials to make bioweapons is an important strategy for preventing the proliferation of bioweapons, this policy would appear to be a very wise strategy for preventing bioterrorism, and should be endorsed by scientists.

Rules that restrict access to select agents can have some negative impacts on scientific research, however. First, treating some people from particular countries as restricted persons conflicts with the norms of openness, non-discrimination, and collegiality that are essential to the academic ethos. Universities have a long tradition of allowing people to pursue education or research on campus, irrespective of their nationality, ethnicity, or culture. Scientists also have a long tradition of sharing data, ideas, materials, and tools without consideration of nationality, ethnicity, or culture [Merton, 1973].

Second, the Patriot Act's list of restricted people may not be very effective. Under the Patriot Act, a restricted person is someone who is an alien, other than an alien admitted for permanent residence, who comes from a country that repeatedly has supported acts of international terrorism [AAUP, 2003]. The U.S. government has developed a list of countries that sponsor or support terrorism, which includes Iran, Iraq, Syria, North Korea, Libya, Cuba, and Sudan [U.S. State Department, 2004]. The problem with this list is that it is a very imprecise tool for preventing terrorists from acquiring restricted agents because there are many potential terrorists who do not come from these countries and most of the scientists in countries that sponsor terrorism have nothing to do with terrorism. Terrorists have conducted activities in Germany, Spain, Russia, and many other countries that do not sponsor terrorism, and there are many peaceful scientists in countries that sponsor terrorism.

Rather than creating a list of restricted persons based on nationality, a more effective way of preventing terrorists from acquiring restricted agents would be to create a list of restricted persons based on analysis of the threat that they pose to security. To determine whether someone poses a security threat, it would be necessary to conduct extensive background checks on that person and to monitor that person's activities. This strategy would require more labor and oversight than a strategy that relies only on nationality, and could threaten the privacy of researchers, but it would be worth the effort. While it is very important to protect privacy, it is reasonable to expect people to voluntarily relinquish some privacy when they participate in activities that raise national or international security concerns, such as working in law enforcement or espionage, or working with restricted nuclear or biological materials.

One final problem with rules concerning restricted agents and restricted persons is that they have become very burdensome for many researchers and research institutions. In addition to requiring institutions to track agents and people, the rules require biosafety plans, safety and security inspections, agent transfer rules, risk assessments of individuals with access to restricted agents, and restrictions on some types of experiments. Consequently, many scientists and universities have decided to not pursue research on restricted agents, in order to avoid this regulatory burden [Gaudioso and Salerno, 2004]. To allow for more flexibility concerning access to biological materials and to reduce the regulatory burden on research institutions, it may be appropriate to take steps to simplify and clarify these rules. We realize that this task may not be possible, since rules always create administrative burdens, but it is at least worth trying.

The Duty to Report Suspicious Activities

Many terrorists have attended colleges, universities, or technical schools. For example, several of the terrorists responsible for the September 11 attacks were engineering students, and others attended flight schools. Documents discovered in an al Qaida training camp in Afghanistan indicate that this organization had relied on information gathered at scientific meetings to establish a bioweapons program, and that the organization was planning to recruit scientists with the required training and expertise to make bioweapons [Petro and Relman, 2003]. There is substantial evidence that the person responsible for the anthrax attacks has had some education biotechnology or microbiology [NRC, 2003]. Even though a great deal of information related to bioweapons is available to the public, it still takes considerable education and training to use that information effectively. Manufacturing an effective bioweapon is not as easy as strapping dynamite on one's chest or making a bomb out of fertilizer. Terrorists (or those who would aid terrorists) may decide to attend colleges and universities to acquire the knowledge and experience they need to achieve their aims. Since scientists may come into contact with people who are planning acts of terrorism, they have an ethical obligation to report any suspicious activities to the appropriate authorities. They, like ordinary citizens, should be mindful of conduct that appears to be preparation for an act of terror. Scientists have the opportunity to nip terrorist acts in the bud.

The obligation to report suspicious activities can raise some ethical dilemmas and problems for scientists and research institutions. First, it could exacerbate discrimination and bias against Muslim, Arabic, or other researchers who might fit the profile of someone who might have links to terrorism. Adhering to the obligation to report suspicious activities could also make it even more difficult for foreign students or scientists to study or work in the United States, because they might come under increased scrutiny. One way to avoid this problem is to distinguish between suspicious *persons* and suspicious *activities*. Scientists would have an obligation to report suspicious activities, not suspicious persons. Scientists should base their decisions to report suspicious activities on objectively observable behaviors, not on subjective impressions or cultural, religious, or ethnic prejudices. To apply this distinction to real cases, scientists need to develop a list of suspicious activities. The list could include some general activities, such as fundraising for terrorist organizations, as well as discipline-specific activities. For example, a person who makes a request for restricted agent, without an adequate scientific reason, would be engaging in a suspicious activity. Likewise, a person who makes inquiries about weaponizing restricted (or unrestricted) agents for no valid scientific purpose would also be engaging in a suspicious activity. Someone who studies vulnerabilities in the food or water safety systems, for no apparent useful purpose, would be engaging in a suspicious activity. While we will not discuss the details of such a list here, we encourage others, especially those who are in charge security and defense, to tackle this evolving problem.

A second potential problem with reporting suspicious activities is that it transforms scientists into law enforcement agents or spies, which can undermine collegiality, trust, and openness, and can promote an atmosphere of suspicion and distrust. The issue of enforcing laws and reporting illegal or unethical behavior is not new, and scientists have struggled with this issue for years. Although most scientists are not comfortable with the role of whistleblower, most have come to accept the idea that they have an obligation to report scientific misconduct, such as fabrication, falsification, plagiarism, as well as financial fraud and abuse and violations of laws that protect human or animal subjects [Shamoo and Resnik, 2003; NAS, 1992]. However, reporting suspicious activity is fraught with more peril than reporting conduct that is patently unethical or illegal, because in many cases the person engaging in the activity may not have done anything clearly unethical or illegal, even though it may appear that they are planning to do something that threatens society. It would take only a few cases of false or frivolous reports of suspicious activity to challenge the wisdom of this approach. Thus, we recommend that scientists proceed very carefully when they report such activities, making sure that they have all the facts and are not jumping to conclusions. We also recommend that research institutions take steps to protect the privacy of both the accuser and the accused in this process. Society should not trample of the rights of innocent people in pursuit of policies that may (or may not) prevent bioterrorism.

One additional problem with reporting suspicious activities is the question of who would receive such reports. Research institutions currently have mechanisms in place for reporting unethical or illegal conduct, such as financial mismanagement or fraud, research misconduct, and so on. But there are no mechanisms in place at research institutions for reporting suspicious activities related to preparation for bioterrorism. A natural choice for a person to receive such reports would be the biosafety officer at the institution. The biosafety officer could share information with other authorities within the institution, which would relay information to law enforcement, national security, or intelligence agencies. The biosafety officer could also help institutions to establish policies and procedures for reporting suspicious activities.

The Duty to Advocate for Research to Respond to Bioterrorism

Since biomedical scientists have an obligation to help address the threat of bioterrorism, they should advocate for research on bioterrorism. Biomedical scientists (and research institutions) should urge the government to provide adequate funding for research on ways of preventing, deterring, detecting, or responding to bioterrorism. Biomedical scientists should also urge the government to establish the proper level of classification for this research. While much of the research related to bioterrorism should be unclassified and available to the public, it may be necessary to treat some research as classified in order to avoid promoting terrorism or aiding terrorists. Scientists should defend classified research, when classification is appropriate.

The obligation to advocate for research to prevent bioterrorism may create some of its own problems and dilemmas. The first problem with additional research related to bioterrorism is that it may take away funds from other worthy research goals. Since September 11, 2001, the United States has drastically increased the amount of money it spends on research related to preventing and combating terrorism. In 2003, the United States spent $2.4 billion on research efforts related to terrorism, including $1.7 billion allocated to the National Institutes of Health and $420 million allocated to the Department of Defense [Malakoff, 2002a]. Two recent legislative measures considered by the U.S. Congress, "Bioshield" and "Rapid Cures Act," would accelerate research on bioterrorism agents as well as measures to prevent or combat bioterrorism [Heil, 2003; Turner, 2004; Fiorill, 2004].

Money spent on bioterrorism prevention research is money that may not be spent on cancer, diabetes, human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS), malaria, and other worthwhile medical and public health problems. Where should bioeterrorism prevention fall on the scale of biomedical research priorities? This question raises difficult problems concerning the relationship between social justice, public health, and national security. Different people may come up with different answers to this question, depending on how they set research their priorities [Dresser, 2001].

Some biomedical researchers have argued that it would be wiser to spend more money on known diseases that kill millions of people each year, such as rotavirus or malaria, than to spend more money on speculative threats that may only kill dozens or hundreds of people, such as bioterrorism [Glass, 2004]. Although bioterrorism may not kill millions of people, it can have a variety of adverse social and economic effects, including public anxiety or hysteria, disruption of trade and commerce, and negative impacts on tourism and financial markets. One must consider these factors as well when deciding whether to spend research funds on terrorism prevention. Although bioterrorism may pose less of a public health threat than influenza, its potential social and economic impacts on society are much greater. Moreover, research on bioterrorism prevention may have positive impacts beyond preventing or responding to bioterrorism, such as helping scientists gain a better understanding of pathogens. Research on preventing the transmission of smallpox may help scientists understand other viruses, such as HIV and influenza.

The obligation to advocate for classified research, where appropriate, may also create some problems. Many universities do not allow classified research to be conducted on campus because it threatens the ethic of openness. These institutions do not accept any restrictions on the publication of results generated through government grants or contracts. A scientist who advocates for classified research may find himself (or herself) at odds with institutional policies and officials. He (or she) may have to decide whether to encourage his (or her) institution to change its policies and allow classified research. Many universities have begun to review their policies on classified research in the wake of the September 11 terrorist attacks [Malakoff, 2002b]. Although government and private laboratories currently conduct most of the classified research sponsored by the U.S. government, it may be desirable to increase the involvement of universities in classified research to take advantage of the knowledge and expertise of academic researchers. If universities do not allow classified research related to bioterrorism prevention to be conducted on campus, then researchers who are interested in this kind of work may have to choose between foregoing this research or leaving their campuses for government or private labs.

While we recognize the difficulties inherent in conducting classified research on university campuses, we think that such research can and should take place, given appropriate rules. The rules should establish procedures for protecting classified data and for ensuring that classified research does not undermine publication of non-classified research. The rules should also protect the educational goals of the institution. For instance, graduate students should not be allowed to work on classified projects if the work will prevent them from publishing results that they need to publish to advance their careers. The rules would be similar, in many ways, to the rules that universities have adopted for conducting secret research for industry [Shamoo and Resnik, 2003].

A third problem with advocating for more spending money on research on preventing or responding to bioterrorism is that this research may increase the likelihood that scientists who have sympathies with terrorists organizations will use their knowledge and expertise to help terrorist organizations. Also, research on preventing bioterrorism may create biosafety concerns, since scientists may accidentally release dangerous pathogens, such as ebola or smallpox in the course of their studies [Shane, 2004]. We recognize the possibility of these harmful results but we do not think that they constitute a good reason to not spend money on bioterrorism research. The best way to deal with these problems is to carefully select and monitor researchers, and to ensure that research is conducted in laboratories that are safe and secure.

The Duty to Inform the Public About Bioterrorism

An important part of the duty of social responsibility is the obligation to inform and educate the public about the consequences of one's research [Shamoo and Resnik, 2003]. Scientists have a duty to provide the public with information related to health and safety, resource use, population growth, the environment, crime, economic activity, and many other areas that raise important political and policy issues. Scientists can provide this information by communicating with media, testifying on expert panels or in the courtroom, giving public lectures or programs, or authoring popular works. If a biomedical scientist has some knowledge or expertise that the public can use to address the problem of bioterrorism, then he (or she) has an obligation to share that knowledge and expertise with the public.

The duty to inform the public can also give rise to ethical dilemmas and issues. First, the public and the press may misunderstand, misinterpret, or misapply information that scientists share on bioterrorism. For example, during the anthrax attacks in the Fall of 2001, many people with no exposure to anthrax spores began taking antibiotics to prevent an anthrax infection [Resnik and De Ville, 2002]. People made the decision to take these drugs based on reports that some people who had been exposed to anthrax were taking antibiotics as a prophylactic measure. The people who took antibiotics even though they were not exposed to anthrax did not understand the personal health and public health dangers of taking antibiotics without a legitimate medical reason. For instance, people can have allergic reactions to antibiotics and overuse of antibiotics can lead to the development of antibiotic-resistant bacteria. Scientists must guard against problems like these when they share information with the press and the public. To do this, scientists must present information to the press and the public in such a way that it is easy to understand, interpret, and apply. They must explain complex concepts and theories in simple terms, and they must express their ideas in non-technical language [Resnik, 2001].

Second, terrorists may be able to exploit sensitive information that is communicated to the public. To avoid providing terrorists with useful information, scientists must consider the benefits and risks of disclosing information to the general public, as they would also consider the benefits and risks of sharing information with their peers. If necessary, the government may also play a role in controlling the dissemination of information to the public. Although some types of information may be more sensitive than other types of information, decisions concerning restrictions on information should be handled on a case-by-case basis.

The Duty to Help Develop Policies Related to Bioterrorism

Biomedical scientists also have an obligation to share their knowledge and expertise with policy makers to help develop regulations and laws related to bioterrorism, such as research priority setting, vaccine development and deployment, control of dangerous information, and access to select agents. Scientists can help policy makers balance the need to respond to the threat of bioterrorism with the need to safeguard the values and norms of science. Input from scientists is important at all stages of policy development, including enacting new laws or updating old ones, making adjustments to laws that have been recently passed, or interpreting and applying laws. So far, scientists have been willing to provide valuable advice to policy makers [NRC, 2003]. It is important for this dialogue between biomedical scientists and policy makers to continue as long as there is a need to address the threat of bioterrorism.

The Duty to Educate Researchers and Students

Scientists have an ethical duty to educate themselves, students, and other subordinates in the responsible conduct of research (RCR). Education in RCR promotes integrity in science and helps to establish an ethical culture [Shamoo and Resnik, 2003; NAS, 2002]. Since responding to bioterrorism is part of the responsible conduct of biomedical research, biomedical scientists have a duty to educate undergraduate, graduate, and post-doctoral students, colleagues, and technicians about different aspects of bioterrorism, including the nature of the threat, the ethical duty to respond to this threat, legal and regulations that pertain to bioterrorism, as well as ethical and legal issues related to responding to bioterrorism [NRC, 2003]. Scientists can achieve these educational goals in many different ways, ranging from sponsoring lectures and workshops, to special seminars, to informal discussions in the workplace or classroom. Universities, government agencies, and professional societies should also support these educational goals by providing encouragement and support for scientists who engage in these activities.

CONCLUSIONS

The threat of bioterrorism is a serious issue in biomedical research, which requires thoughtful discussion and debate. Biomedical scientists can play a very important role in preventing and responding to bioterrorism. Biomedical scientists, both collectively and individually, have many different ethical responsibilities related to addressing the threat of bioterrorism, including the duty to not conduct dangerous research, the duty to not publish dangerous research, the duty to not disclose classified research, the duty to report suspicious activities, the duty to not share dangerous biological materials, the duty to advocate for research, the duty to educate the public, the duty to help with policy development, and the duty to educate researchers and students. Scientists should work with universities, government agencies, private companies, journals, and professional societies in responding to the threat of bioterrorism.

Any policy or strategy for dealing with bioterrorism must find a way of responding to the inherent conflict between scientific norms and individual rights and the need to promote national and international security. To deal effectively with the threat of bioterrorism, scientists must adhere to some rules, such as restrictions on some types of publication, that conflict with scientific norms, such as openness. In this article, we have proposed some policies and recommendations that attempt to strike a fair and reasonable balance between protecting scientific norms and individual rights and promoting national and international security. Sometimes it may be difficult to establish an appropriate balance between the need to prevent bioterrorism and the need to protect scientific values and individual rights, but scientists and policy makers must strive to do so. Biomedical research should not be sacrificed in the struggle against terrorism.

We agree with the NRC's recommendations concerning the importance of educating researchers in scientific and ethical issues related to bioterrorism. Since education in the RCR often does not take place in the absence of clear governmental and institutional mandates, we recommend that the U.S. government require that all researchers and students, who are conducting research sponsored by the government related to bioterrorism, have education in RCR as it relates to bioterrorism. This education should include education not only in scientific responsibility, but also in other aspects of RCR, such as data integrity and management, authorship, animal research, human research, and so on. All of these issues related to RCR become more significant and consequential when one is conducting research that poses security risks. We also recommend that this education requirement should be implemented by the Office of Research Integrity (ORI) in the Department of Health and Human Services. Furthermore, the ORI should add education in ethical issues related to bioterrorism to its list of requirement training for students working on Public Health Services training grants.

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