

A Multidisciplinary Approach to an Ethic of Biodefense and Bioterrorism

Victoria Sutton

The normative approach to defining an ethic of a field, which focuses on one disciplinary field, requires modification in the consideration of a biodefense ethic to include not one discipline, but many. The consideration of an ethic in biodefense must capture issues in a multidisciplinary scope, including the ethical studies in the disciplines of medicine, sciences, technology, law, international relations, public health, environment, and war, each having their unique framework of ethical constructs.

An ethic of bioterrorism and biodefense raises issues which can be examined utilizing multidisciplinary ethical considerations. The disciplines of medicine, sciences, technology, law, international relations, public health, environment, and war each have a framework of ethical principles which are essential in the scope of ethics which are incident to bioterrorism and biodefense; the absence of any one of which would create a void in our understanding of the complexity of this subject.

This examination of these disparate systems of ethics from many disciplines asks the question: what is different about the ethical issues raised in the context of bioterrorism and biodefense which require this examination? This examination suggests that rather than an interdisciplinary ethic, there exists a multidisciplinary set of ethical principles drawn from many fields needed to understand an ethic of bioterrorism and biodefense.

This is an analysis which would not be well-served without an examination of the various fields of ethics, from a historical perspective, noting mergers of these

fields in a process of their development based on experiences over time.

This analysis begins with an introduction examining the question of interdisciplinarity among the ethical systems considered. Second, an examination of the areas of bioethics, public health ethics, governmental ethics, international relational ethics, environmental ethics, and the ethics of the conduct of war are each examined for their application to bioterrorism and biodefense. Third, the distinctions of bioterrorism and biodefense from other issues are examined. Fourth, the proposal for a framework for an ethic to address bioterrorism and biodefense is considered, based upon organizational perspectives. Bioethicists have urged that the area of ethics in bioterrorism and biodefense is an area which should not be ignored,¹ and this article begins to examine what might be considered a multidisciplinary framework for a biodefense ethic.

Do We Need a Biodefense Ethic?

Eight questions suggest that a biodefense ethic is distinct from other fields of ethics. These eight questions define the scope of biodefense activities which would be well-served by an ethical framework shaped to address the questions in the area of biodefense.

First, the question must be asked as to whether ethics, or the tools of ethics, should change at all during war or emergencies? Does war or an emergency change our approach? To the extent that survival of the nation depends upon biodefense and our actions in that context, it adds to the outcome of the individual and of the public health, as well as the security of the nation. Some experts in the field are concerned that ethics will be compromised in a time of war,² and that thinking about these problems during peacetime

Victoria Sutton, M.P.A., Ph.D., J.D. is Professor of Law and Director of the Center for Biodefense, Law and Public Policy, Texas Tech University School of Law.

will help to resolve that risk. The public health model proposed by Buchanan,³ which challenges the model where the individual interest is subordinated to the interest of the common good in a cost-benefit balancing test, is insufficient to consider not only the interest of the individual, the interest of the common good in public health, and also the interest in the preservation of the government in the context of biodefense bioethics.

Second, in the context of biodefense and bioterrorism, the uncertainty is tremendous. The risk, the extent of the attack, the diagnosis, treatment, and prophylaxis is highly uncertain, leaving decisionmaking with little solid ground. In the early stage of an attack, decisions concerning the first to receive treatment or prophylaxis must be addressed in the context of this great uncertainty. A triage model for who receives what treatment is important to consider. The utilitarian approach (in the sense of consequences outcome) suggests those who can satisfy medical needs of others must be treated first, receive the prophylaxis, particularly if it is in short supply.⁴ The Kantian or nonconsequentialist model suggests that rules should be determined such as “first come, first served,” ability to pay, or a lottery system.⁵ The degree of uncertainty of bioterrorism may lead to application of the Kantian approach to provide some predictability to a highly uncertain context; or it could indicate the consequentialist approach, where the attack requires the abandonment of previous rules for a better outcome, should the unpredictable occur.

The legal concept of the duty to face danger will be affected by the tremendous degree of uncertainty, not present in understanding the risks in the case of HIV, for example. The 2001 American Nursing Association Code of Ethics and the 1994 American Nursing Association Risk versus Responsibility Statement both encourage nurses to provide care despite personal danger, requiring nurses to balance the risk-to-self with the need to provide care. The tremendous uncertainty in biodefense makes it difficult to make this assessment.⁶ Contrasting this responsibility with that of the American Medical Association code of ethics for physicians, which dropped the language “responsibility to provide treatment” in the 1950s, it is notable that there is little in the code creating a duty for physicians. However, after September 11, 2001, the AMA’s Council on Ethical and Judicial Affairs issued a “Declaration of Responsibility,” in response to the threat of bioterrorism, requiring physicians to “[a]pply our knowledge and skills when needed, though doing so may put us at risk.”⁷ The term “risk” is

not defined, but may be interpreted as the balance of the risk to the physician against the potential benefits to the patient⁸ or perhaps to many patients. Nurses and other medical personnel believe that their code of ethics does not permit them to refuse to treat, whereas physicians’ code is merely voluntary or aspirational.⁹ The Model State Emergency Health Powers Act (MSEHPA) developed for the Centers for Disease Control and Prevention and the National Governors Association,¹⁰ is a proposed codification of the duty to treat, which would create a legal duty, where none currently exists in common law.¹¹ This statute would codify state power to require health-care providers to provide care in the event of a health emergency, such as a bioterrorism event.

Biodefense research is a double-edged sword. Research in the area of biodefense can be used for altruistic purposes, or the same research could be used for the destruction of humankind.

Third, the policy to just “do the right thing” may not be sufficient in the context of biodefense. Concern that the fluidity of a bioterrorism event does not lend itself well to just “doing the right thing,” because the right thing may change during the development of an attack.¹²

Fourth, biodefense research is a double-edged sword. Research in the area of biodefense can be used for altruistic purposes, or the same research could be used for the destruction of humankind. Some have suggested that an ethical problem exists where much biomedical research money has shifted to work in biodefense from other areas of medical need, yet researchers are, by necessity, driven toward areas for which there is existing funding with the clear understanding that the reason they could work in those areas, was because of the availability of funding.

Fifth, human subject research is particularly difficult because for the individual the consequences can be catastrophic and highly uncertain; and for the public, experimentation on large populations precludes traditional, individual informed consent measures, with often unknown consequences. Human subject research in biodefense has two distinct components requiring analysis: individual human testing and population experiments.

The development of the Common Rule,¹³ which governs the conduct of human subject research for all federally-funded research from all federal agencies, was never designed with population research in mind,¹⁴ therefore it is difficult to determine when pub-

lic health programs are research programs or treatment programs. It has been suggested that focusing on the word “design” in the Common Rule, the primary intent of the program, will be determinative. If the program is serving populations for their own benefit, or the community benefit, then it is a treatment program; however, if the primary intent is to collect data to answer a scientific question, then the program may be a research program.¹⁵

The use of human subjects in individual testing with the premise of the importance of concept of “consent” divides the world of subjects among groups with varying degrees of ability to grant true consent. These groups include civilians, military personnel, prisoners, mentally impaired, non-Americans, and the young and the old. For purposes of biodefense research, civilians, military personnel and non-

other countries.¹⁷ The Convention on Human Rights and Biomedicine (CHRB), also called the Bioethics Convention, is the first binding international agreement to create ethical principles for the conduct of externally funded research, now signed by thirteen countries.¹⁸ However, enforcement of individual researchers’ agreements is difficult to monitor. For example, in one case, an agreement between the Government of Tanzania and an individual researcher, testing the efficacy of different antibiotics in plague infections provided only that the researcher provide the medical officer with the results of the study. The informed consent document used was simply an agreement to treat. However, the difficulty in explaining the consequences and risks of treatment to a population that may believe strongly in the evil eye as the source of their illness, creates an ethical paradox that

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Americans are the primary groups of concern, although any of the aforementioned groups may be part of biodefense research.

Civilians and military personnel both must grant informed consent, and the Common Rule is intended to apply to both groups; however, the ability to grant true consent by military personnel is clouded by the requirement for military personnel to obey orders and the consequences of refusing even requests to perform duties and services for the national defense. The Medical Research Volunteer Subjects (MRVS) are a corps of military personnel who are trained as research assistants, but who volunteer as human subjects for biodefense research, and best illustrate the high standard of consent that should be expected in human subject research and informed consent in biodefense research. This group has been said to “come as close to realizing the ethical ideal of true informed consent as any group of research subjects since Walter Reed’s Yellow Fever Commission.”¹⁶

Whether the standards should be different for human subject research in the United States verses other countries must also be considered, and should ideally be resolved by the balancing of risk to the individual. Guidelines created by the International Medical Societies address conditions for which externally funded research may utilize human subjects in

require different standards for human subject research in other countries because obtaining informed consent may not be possible.¹⁹

Sixth, the environmental consequences of engineering nature or destroying nature inevitably requires an examination of the consequences of such acts of finality for the world. In the context of biodefense, the consequences of eliminating species or creating new chimeras (i.e., engineered organisms that do not exist naturally), requires consideration of ethical guidance to inform decisions that will impact survival of human populations within the environment that is created by such decisions. The potential for environmental bioterrorism can create economic and health consequences which may be permanent and devastating. This may present a threat in the form of agroterrorism, or water contamination, the utilization of the environment as the vector or reservoir for agents that can cause serious health consequences and hopelessly contaminated environments.

Seventh, bioterrorism is global and does not recognize jurisdictional boundaries. The global nature of biological agents requires that we establish some form of protocol of ethical behavior among countries. The recent outbreak of SARS in southern China was kept secret by the Chinese government for a period of time which proved catastrophic to efforts to contain the

contagion. The World Health Organization (WHO) was alerted to investigate the outbreak, which has been their chartered role through the United Nations, leading to efforts to limit the worldwide spread of the highly contagious respiratory virus. Earlier disclosure by the Chinese government would have provided a much needed window for containment before the disease reached several continents. Security and health have become increasingly linked, as evidenced by the recent report from the Commission on Human Security, which included a chapter that focused on the link between human security and international public health.²⁰

Our relationship with other countries in our use of investigational new drugs in biodefense and public health should also be managed with binding international guidelines,²¹ rather than by individual researchers or entrepreneurs from the U.S. seeking human subjects in countries other than the United States, where they may circumvent the guidance on the basis of the benefit to society. In countries where natural outbreaks of diseases that can be used as biological weapons, for example, plague in Tanzania and Madagascar, it is not only reasonable, but vital to assist those populations and to utilize the results of those treatments.²²

Eighth, and finally, because bioethicists have suggested that the area of biodefense is an area of bioethics that should not be ignored,²³ we must take this opportunity to make the necessary assessments and create a biodefense ethical framework, not in the heat of a biowar.

The Development and Principles of Relevant Fields of Ethics and their Contributions to a Biodefense Ethic

An ethic has been described as “a limitation on freedom of action in the struggle for existence.”²⁴ In application, an ethic is the acceptance of a behavior by society. A biodefense ethic would address the continuity of life and coexistence of humankind in a common environment in a manner agreed to by the international community, cognizant of the motivation for research in sciences and engineering fields which contribute to biodefense or bioterrorism, the use of human subjects to test countermeasures, public health cooperation, governmental ethics, and individual governmental officials ethics, in a national security and homeland security plan which protect civilians as well as military personnel, while balancing (without compromise) the rights and responsibilities of all parties.

This working definition of a biodefense ethic cannot be examined without consideration of the fields of these areas of ethic studies which have earned a substantive role in a biodefense ethic, which include:

bioethics, medical ethics, public health ethics, environmental ethics, governmental ethics, international relational ethics,²⁵ and ethics in the conduct of warfare.

It would mean little to begin an assessment of ethics in biodefense and bioterrorism without understanding the development of the various fields which converge in this age of terrorism, which form at this moment in time, to create a comprehensive set of multidisciplinary ethics, relevant to understanding bioterrorism and biodefense.

Bioethics

Bioethics comprise a large scope of activities within the rubric of biodefense, but may be examined first in the context of human subjects in experimentation. Because of the effort of bioterrorists to disperse bioweapon agents over large populations, human subject experimentation must be done on populations as well as on individuals. Each of these areas raises unique considerations.

Experimentation on Individuals

Out of war arose a milestone in bioethics in the development of the Nuremberg Code from the war crimes trials (1939-1945) for atrocities in human research that occurred during World War II.

In 1966, the matter of human subject research was questioned with the publication of an article by Henry Beecher, a physician at the Harvard Medical School, entitled “Experimentation in Man,” in the *Journal of the American Medical Association*. His article focused on the abuses of human subjects in research universities and institutions and, in particular, on the experimentation on these human subjects without the subject’s knowledge and consent.²⁶ This was a landmark event in our concept of an ethic regarding the treatment of human subjects.

In 1972, the United States Congress acted to end a research project, the Tuskegee Study, sponsored by the United States Public Health Service. The study, which had begun in 1932, followed the course of syphilis in black males but failed to disclose diagnostic information and even effective treatment in order to clandestinely ensure the continued participation of the men. This incident led to the development of federal regulations for the use of human subjects and the requirement of informed consent from participants in any federally funded research. The use of human subjects in biodefense research has followed a similar path, except that the secrecy of military experimentation has succeeded in shrouding human subject research in the interest of national security. Recent litigation from radiological experiments²⁷ and LSD experiments on military personnel demonstrate that human

subject experimentation, found to be unethical where public debate was considered, was otherwise continued somewhat unabated in the military context.

The use of human subjects in biodefense is particularly important because of the sensational and catastrophic implications to the individual and, partly for that reason, the U.S. has responded by creating a unique corps of military personnel who comprise what is arguably the most well-informed corps of human subjects for testing ever comprised. Laboratory assistants at the USAMRIID, approximately seventy Medical Research Volunteer Subjects (MRVS), utilized for the first phase of clinical trials in the testing of vaccines and drugs,²⁸ represent the effort to correct past misuses of human subjects with what many have seen as a model program.²⁹ Human subject testing in perhaps the most brutal of all medical challenges – bioterrorism – had moved from moral outrage to a controlled and regulated approach, based on an ethic of human subject research.

Experimentation on Populations

Experimentation on populations is inevitable in biodefense research. It cannot include the informed consent of every individual in the population because the procedure of obtaining consent would likely destroy the experiment: the behavior of the participants would likely be altered, and many could be expected to flee to avoid exposure to the unknown consequences of an experiment. The death of Edward Nevin was one such probable consequence of the clandestine experiment in the San Francisco Bay Area in 1950, which used *serratia marcescens* bacteria to trace the susceptibility of the population to a possible biological attack. Although the bacteria was recommended by a scientific and medical advisory group to General McAuliffe, it was subsequently found to be a lethal bacteria when exposed to open wounds and the resulting anaerobic conditions when the wounds were closed. Relatives of Edward Nevin filed suit against the United States for wrongful death under the Federal Torts Claims Act.³⁰ The appeals court vacated the district court's holding that the act of General McAuliffe was one within the discretionary function exemption³¹ of the Federal Tort Claims Act. The appeals court remanded with instructions, instead, to dismiss the case for lack of subject matter jurisdiction, finding that the case should have been decided based upon whether the discretionary function exemption applied, answering the subject matter jurisdiction question.³² This, the wrongful death question, evaded examination.

Human Frontiers of Science

The 1960s and 1970s marked the beginning of a societal struggle in medicine and in the courtroom to find a resolution to the issue of abortion.³³ On the bioterrorism front, the year 1969 was a landmark year in biological warfare, when President Nixon announced that the United States would no longer engage in a research program in biological warfare, saying that "Mankind already carries in its own hands too many of the seeds of its own destruction."³⁴ In 1972, the United States signed the treaty which ended the U.S. offensive program, as well as other members of the world community.³⁵ The Senate ratified the Biological Warfare Convention in 1974 as well as the earlier Geneva Protocol. President Gerald R. Ford signed both in 1975.³⁶ Clearly, the U.S. ethic had changed from the 1925 conclusion that the moral importance of a ban of bioweapons did not outweigh the interest in the use of bioweapons for national security.

As the biotechnology revolution was unfolding, a legal resolution was again sought in a range of issues raising bioethical concerns in the right to end one's life,³⁷ the right to terminate a life,³⁸ as well as the use of stem cells in research in the period from the late 1980s through the 1990s. A federal moratorium on funding for all stem cell research was enacted during the Bush Administration. The Clinton Administration appointed the National Bioethics Commission to study such issues, after the cloning of Dolly the sheep, and based upon their advice, President Clinton extended funding for stem cell research throughout the 1990s. Uses of biotechnology that were far darker were brewing in the world.

First, President George H. W. Bush prohibited the use of aborted fetuses as a source for embryonic stem cells; second, President William Clinton did not object to stem cell research, but prohibited federal support of cloning research; and third, President George W. Bush limited stem cell research to sixty approved lines, derived from mouse cells only. So in early 2001, the third President of the United States to be the *de facto* arbiter of bioethics in research, made the issue of limiting stem cell research a priority for his Administration. One of the first decisions made by President Bush was to redefine what stem cell lines could be used under federal research grants, in an effort to respond to concerns that stem cells derived from aborted fetuses would be used. While grappling with these distinctions in stem cells, attention turned to the dark side of biology in the United States during the anthrax attacks, which followed the September 11, 2001 commercial airline terror attack on the World Trade Center in New York and the Pentagon in Washington, D.C.

The following observation was made by Jonathan Moreno, a bioethicist concerning the post-9/11 impact on the field of bioethics:

Bioethics as a field has been fortunate that its values and concerns have mirrored the values and concerns of society. In light of the September 11th attacks, it is possible that we are witnessing the beginning of a transition in American culture, one fraught with implications for bioethics. The emphasis on autonomy and individual rights may come to be tempered by greater concern over the collective good. Increased emphasis on solidarity over autonomy could greatly alter public response to research abuses aimed at defense from bioterrorism, to privacy of genetic information, and to control of private medical resources to protect the public health.³⁹

The tools of ethics and bioethics provide us with standards and a framework for examining these new problems of bioterrorism. There are two contrasting considerations in the structure of moral issues used by bioethicists. First, the utilitarianist and the nonconsequentialist approaches focus on the individual. The utilitarian or consequentialist approach judges actions based upon their consequences to the individual; the rightness of the action then results in the greatest balance of good, happiness and satisfaction over evil and dissatisfaction, when compared to any alternative.⁴⁰ Second, the nonconsequentialist approach considers consequences, but primarily focuses on the reference to rules or standards that are not necessarily linked to consequences. Deontological theories, with their basis in a duty owed, lead to the application of standards or rules in the context of a duty owed to another or to society, and can be repeatedly applied to similar situations.⁴¹ The variations on these two approaches are many, and the overlap makes them almost indiscernible in some discussions.

The use of past experiences and decisions in the context of ethical problems and mass disease outbreaks, for example, the experiences with HIV, Yellow Fever, the Flu pandemic of 1918, and the anthrax attacks in 2001 can be used to frame the kinds of problems that must be addressed. The utilitarian approach will ask what are the right actions for the benefit of the individual, while the Kantian or non-consequentialist approach asks what rules should be consistently applied for the good of the public. These questions can be readily seen in the decision whether to initiate a nationwide smallpox vaccination program, where the individual consequences for some will be serious injury and death; but the approach to

defending the nation and the health of the public and the military suggests that we take a prophylactic action.

Public Health Ethics

In 2002, several scholars from fields of law and bioethics began to address an emerging field of public health ethics, taking some principles from bioethics within the context of the role of the public health as distinct from the health of the individual patient,⁴² creating a new set of principles distinct from bioethics as a field predominately focused on the individual, rather than the public or the government.

The anthrax attacks and the many responses to the threat of bioterrorism have challenged us to examine what ethical thought should shadow or precede our actions, and the correlation of these fields of ethics is key to our understanding and development of a biodefense ethic.

A new and emerging area of ethics is that of public health ethics.⁴³ Not until recently have bioethicists devoted attention to the understanding of ethics in public health law as distinct from ethics in the practice of medicine and bioethics, particularly in relation to individuals.⁴⁴ Recent scholarship suggests that it is appropriate to develop a new public health ethic,⁴⁵ while pointing out that there are overlapping fields of ethics that require further work in areas of public health such as human subject research in public health practice.⁴⁶

Public health ethics is thought of from three perspectives: professional ethics, applied ethics, and advocacy ethics. The professional ethic is concerned with the behavior of the professional in public health and the reliance of society on the integrity of public health professionals to act in the best interest of society.⁴⁷ The applied ethics approach considers specific applications of ethical principles to concrete examples, using a cost-benefit or cost-effectiveness approach, subordinating the individual to the interests of the common good.⁴⁸ The advocacy ethic seeks to achieve social justice in community health, focusing on the vast body of literature which shows a positive correlation between socio-economic status and health of individuals or communities.⁴⁹

Among the three perspectives – professional ethic, applied ethic and advocacy ethic – the applied ethic concerning the cost-effectiveness balancing approach is particularly important to a biodefense ethic. One scholar proposes that the assumption of a cost-benefit or cost-effectiveness balancing approach encompasses little or no consideration for the individual,⁵⁰ and in the context of biodefense, the argument that individual interests are subordinated to not only a cost-benefit in the traditional sense of public health, but also

subordinated to a national security interest. Further, an intentional use of a biological agent, because it can be used randomly among many communities or in mass from an aerosol dispersion, can make predicting rates of infection more uncertain, leading to the need to design countermeasures with broader margins of safety. Another problem unique to bioterrorism is that the resources committed to biological agents that pose no natural public health risk, could likely be weapons of choice for the bioterrorist, creating a high cost with a benefit accruing only in the event of a biological attack with that agent, which is widely known to pose only a small risk. The consequences, however, would be catastrophic.

Governmental Ethics

But the obsession with germ warfare continued and led to the “disregard for legal scruples,” as one historian observed.⁵¹ In one instance, the United States faced the moral dilemma of accepting the benefits of the research done in the Japanese biological weapons program, Unit 731, which involved the kind of human experimentation that was unconscionable, in exchange for guaranteed immunity for Japanese war criminals who had engaged in the program.⁵² The United States chose to take the information, finding that the moral obligation to prevent death justified the moral choice of granting freedom to individuals who perpetrated inhuman suffering on other human victims.

Governmental ethics may be thought of in two respects: (1) as the ethic of the individual public servant; or (2) the ethic of the government as a body in its relation to its citizens and to other countries. From the first perspective, the ethic of the individual public servant, three broad considerations have been proposed to evaluate the ethical public servant: “(1) The quality and enforceability of ethics laws; (2) the qualities of the governing system which deter corrupt conduct; and (3) the ability of the governing system to attract ethical individuals as public servants.”⁵³ The role of the government in public health has been described as being “compelled by its role as the elected representative of the community to act affirmatively to promote the health of the people,” even though it “cannot unduly invade individuals’ rights in the name of the communal good,”⁵⁴ and such affirmative action requires an ethical framework for biodefense, rather than a reactive set of policies.

International Relational Ethics

International relations among governments as well as between governments and individual citizens of other countries, includes a human rights ethic among the

important concepts to be included in a biodefense ethic. There are three predominate ethical principles in international relational ethics which are important in a biodefense context: “(1) the inherent worth and dignity of individuals; (2) the community-defined common good; and (3) authentic relationships.”⁵⁵

A human rights ethic in public health law was described from the observation that public health programs which burden human rights to the extent they are human rights violations, “have adverse effects on physical, mental, and social well-being” and that the promotion and protection of human rights is “inextricably linked with promoting and protecting health.”⁵⁶

Environmental Ethics

In the context of our concern for preservation of our species and for purposes of future scientific research, in 1992, the United States agreed to prevent the destruction of what was believed to be the only remaining smallpox virus in the United States, in part because of the desire of environmental groups to promote a policy of preserving all species of life in the world.⁵⁷

An environmental ethic does not prevent the use of natural resources, but does “affirm their right to continued existence, and, at least in spots, their continued existence in a natural state.”⁵⁸ The understanding that the continued existence of the environment is not only essential to the existence of humankind, but to all of the components of the earth which have links to well-being. An environmental ethic is based upon the idea that individuals are dependent upon their community and the pressure to compete and cooperate balances the moral struggles of the individual. The extension of this interdependency to the soil, plants, animals, and water carries the same moral balance and defines the environmental ethic. One such principle of this relationship is the moral direction that “[a] thing is right when it tends to preserve the integrity, stability and beauty of the biotic community. It is wrong when it tends otherwise.”⁵⁹

Ethics of the Conduct of War

The first incident of bioterrorism likely occurred in a world without a firm ethical concept for weighing such considerations. When Hannibal ordered the launch of viper-filled vessels upon enemy ships of Pergamus at Eurymedon in 190 B.C.,⁶⁰ he left us little in the way of an understanding of any moral or ethical considerations that went into his strategy. The action of De Mussis, a Mongol, in catapulting plague-infected corpses over the walls of Kaffa in 1346,⁶¹ calls for a review of the Justinian Code and related codifications in Roman Law, which one finds evidence no prohibitions in the conduct of war. In fact, it was not until the

1500s when the first major work of philosophy in the ethics of war, was crafted by Machiavelli,⁶² summarized by Philip Bobbitt: “[D]eceipt and violence are wrong for an individual, but justified when the prince is acting in behalf of his state...the tactics of the prince, in law and in war, must be measured by a rational assessment of the contribution of those tactics to the strategic goals of statecraft, which are governed by the contingencies of history.”⁶³ Bobbitt finds that Machiavelli and others led a transformation of the military philosophy from that of the religious and the military of the medieval world to that of the strategic and legal in the Renaissance world.

In the 1700s, the countries of Great Britain and the United States carried out a policy of extermination of Native Americans through the use of biological warfare – the intent was not terror, but extermination in order to facilitate the acquisition of indigenous land holdings⁶⁴ – driven by what was later termed the “Manifest Destiny” to settle America. It is not disputed that the strategy was discussed between Sir Jeffrey Amherst and Captain Ecuyer and carried out in the intentional transfer of contaminated handkerchiefs and blankets from the smallpox hospital to the Indians, as documented by the journal entry, “...we gave them two blankets and a handkerchief out of the smallpox hospital. I hope it will have the desired effect.”⁶⁵ This policy of extermination is evident from policy articulated by The Jamestown Colony in 1610, based upon a presumption of a “right of Warre,” by which the colonists would have the right to “invade the Country and destroy them [i.e., Indians]...whereby wee [sic] should enjoy their cultivated places [and] their cleared grounds in all their villages...shall be inhabited by us.”⁶⁶

While the field of ethics in war was in its infancy, the field of bioethics already possessed ancient roots in the Hippocratic Oath. However, it was not until the eighteenth century, when professional codes of ethics were written, in particular the first code of ethics written by the American Medical Association in 1846, in the first articulation of an ethical relationship with the individual patient by a professional, self-regulating body.

In 1863, the Lieber Code was developed in the Lincoln Presidency and established the first modern American code of conduct for armies, implemented during the Civil War. In the first directive prohibiting biological warfare in a modern war, U.S. Army General Order No. 100 issued during the Civil War in 1863, stated: “The use of poison in any manner, be it

to poison wells, or food or arms is wholly excluded from modern warfare.”⁶⁷ The U.S. policy clearly extended its “modern warfare” ethic of war beyond the Civil War to international wars.

At the end of World War I, the Geneva Protocol was signed in 1925 by twenty-eight countries; it condemned the use of chemical or biological warfare. However, the U.S. Senate refused to ratify the Geneva Protocol. U.S. Army historian, Jeffrey Smart wrote that the U.S. Senate apparently concluded that “chemical warfare was no more cruel than any other weapon and therefore should not be banned.”⁶⁸ This is the first international agreement to articulate an ethic of war concerning biological weapons, but the U.S. was reluctant to commit to a ban, presumably in anticipa-

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tion of the need to use them for national security goals. The underlying moral principle: national security justifies the use of bioweapons.

While the benevolent uses of medical knowledge and biotechnology were being debated, the dark side of biology was afoot in America. The utilization of biological weapons by the Rashneeshee cult in The Dalles, Oregon in 1984⁶⁹ demonstrated the risk of domestic bioterrorism faced by the U.S. Driven by religious fervor, this single event in Oregon signaled a beginning of a regression of war strategy back to the medieval world of religiously driven – and justified – war.

The theory of the “just war” is the predominate ethical theory in war, and requires consideration of such issues as the loss of human life, the need to defend a country’s citizens and the need to protect innocent life. Two parts of the “just war” theory are described as (1) when is military force justified (*jus ad bellum*); and (2) how the war is conducted (*jus in bello*). That is, a war cannot be just, even if it is fought for noble causes if it is conducted in an unethical manner. Six conditions are generally considered to be required for a “just war”: (1) it must be for a just cause; (2) it must be officially declared; (3) the goal of the war must be ethical; (4) all other options must be attempted before war; (5) the war must have a reasonable chance of succeeding; and (6) the means must be in proportion to the end sought.⁷⁰

The “doctrine of double effect” a defense for the death of civilians where a legitimate military target is the focus of the attack in consideration of *jus ad bellum*, or how war is conducted. For example, the attack on a military base in a city is a legitimate target although some civilian deaths occur. However, the use of weapons of mass destruction, particularly biological weapons because they are so indiscriminate in the effect on civilian casualties, cannot be considered acceptable under the doctrine of double effect.

The theories of realism and pacifism are also considered in the framework of the ethics of war. Realism suggests that the state is not an individual and must act in ways in which the individual would not act, finding roots in Machiavelli principles.⁷¹ Pacifism finds war unacceptable in any form.

A Framework Proposal for the Consideration of a Biodefense Ethic

How then, can these relevant fields of ethics be integrated in order to inform our consideration of a biodefense ethic? An interdisciplinary approach requires the application of principles of one discipline to another, while a multidisciplinary approach takes the question in components, each of which may be examined using the relevant field of ethics, independent of the other component. For a consideration of a framework for a biodefense ethic, a multidisciplinary approach permits each of the eight questions posed in the beginning of this discussion to be examined under the light of the most relevant ethical discipline.

Where then do you begin an examination in an approach involving independent components of consideration? Using a duty approach, the identification of where a duty to others and to the world may exist, a perspective emerges that can encompass the eight issues posed, as well as the relevant fields of ethics. This approach would include four considerations from the perspectives of where a duty to others and to the world must exist: (1) an international relational ethic; (2) a U.S. governmental relational ethic with the public; (3) a U.S. governmental relational ethic with the military; and (4) a private sector ethic.

An International Biodefense Ethic

The development of an international framework for bioethics in bioterrorism is increasingly necessary because it is evident that one country cannot exist in isolation with its own biodefense ethic and realize its benefits. The Commission on Human Security has begun with a consideration of public health and secu-

urity, but the biodefense ethic encompasses such a wide range of ethical considerations from many fields beyond that of public health which cannot be considered separately to achieve a worldwide biodefense ethic. Such an approach to an international framework should begin with the Kantian nonconsequen-

The development of an international framework for bioethics in bioterrorism is increasingly necessary because it is evident that one country cannot exist in isolation with its own biodefense ethic and realize its benefits.

tialist approach using a standard of duty – a deontological approach. That standard of duty would consider who owed the duty and to whom the duty was owed, including that of one country to the world. For each country, the development of a biodefense bioethic would require at least these three major approaches to duty: (1) a Federal government to military relationship; (2) a Federal government to civilians and the environment, including U.S. citizens, non-U.S. citizens outside the jurisdiction of the U.S., and the environment; and (3) the private sector relationship with individuals, including health-care providers and scientific and medical researchers among the private sector perspectives.

A U.S. Federal Government Biodefense Ethic and the Military

The federal government must consider the risk of death or injury from administering vaccines and drugs to military troops balanced against the risk of death or injury if the bioweapon is used against the troops. The USAMRIID is the national laboratory with a mission specifically to protect our troops against biological and chemical weapons, and requires the same standards of safety and FDA approvals as that of the private sector. New testing protocols have been proposed to use primates rather than humans, in an effort to move forward vaccines and drugs for the protection of the troops, raising new questions of the reliability primates for safety and efficacy trials. Animal rights activists have long opposed the destruction of animals for testing, and the infection of animal subjects with bioweapons raises the concern of pain and suffering of these test subjects.⁷²

A U.S. Federal Government Biodefense Ethic and the Public

Areas for consideration in bioethics in biodefense

from a federal government perspective involve three sets of issues: (1) the bioethical considerations for the citizens of the United States, and; (2) the bioethical considerations for the governments and individuals outside of the United States; and (3) the bioethical considerations for the environment that affect all individuals in the world.

The first type of bioethical consideration for the citizens of the United States includes federal government experimental activities in our national defense – those involving civilians and those involving military troops; federal governmental regulation of vaccines and prescription drugs for biodefense, including the development of those vaccines and drugs. Experimentation includes those experiments on populations and experimentation on individuals.

The Edward Nevin case is an example of the problem of experimentation on the population with what should have been an innocuous bacteria, but proved deadly in Nevin's case. The consideration of race or ethnicity in a response to a disease outbreak is also important. For example, during the outbreak of hanta virus in the Navajo Nation, references by Tom Brokaw and Peter Jennings on NBC and ABC respectively to the "Navajo mystery virus" perpetuated racial tension and divisions in a time of panic. Racially discriminatory policies, such as those which led Arizona police officers to abandon searches for Native Americans – but not for Caucasians – after accidents in 2001 could also lead to cessation of health care in a public health emergency. Such a policy was found to be a violation of the Equal Protection Clause in *Amos v. City of Page, Arizona*,⁷³ where police following policy not to pursue Native Americans after accidents, abandoned the search for a Navajo citizen who left an automobile accident.

The consideration of vaccines and prescription drugs for biodefense requires a balancing of the risks to individuals with the benefit to the whole population receiving the vaccine or treatment. The decision to provide smallpox vaccine to health-care workers in the United States, was a result of the balancing of concerns for public safety and individual safety, as well as one of national security. The move to convene a panel of ethicists by CDC in October 2004, to decide who should have priority for the flu vaccine, was a signal that the federal government is addressing what may be a repeating process in the event of a bioterrorism threat or attack for which there may be a shortage of vaccine.⁷⁴

The second type of bioethical consideration for the governments and individuals outside of the United States includes an area which is largely unregulated. For example, our drug trials for bioweapons defense

may require that we test individuals in other countries where they may be exposed to the diseases which are potential bioweapons. For example, the CDC is currently sponsoring research on antibiotic efficacy on plague, requiring victims of plague which are consequently in other countries, for example Tanzania and Madagascar. Another example is that of the federal government's use of human subject data from other countries that was collected through the commission of war crimes. For example, the perpetrators of Unit 731 in Japan, who were responsible for the collection of much data on bioweapons experimentation on humans and prisoners of war, were protected from prosecution by the United States in exchange for these data for use by the United States.⁷⁵

The third type of bioethical consideration – for the environment that affects all individuals in the world – might, for example, include the consideration of whether to make the smallpox virus extinct by destroying all known samples. The arguments include the moral obligation to preserve all existing species and resist the temptation to make any species extinct, even one that has been deadly to the human species.

A Private Sector Biodefense Ethic

The private sector includes private companies, universities, and research institutions that are engaged in the development of vaccines, drugs, and devices for biodefense. Issues arising in the private sector may include human experimentation and informed consent as well as drug trials on individuals not in the United States.

In the area of health-care providers, many issues arise, which may include the refusal to treat a patient who may be infected, refusal to admit a patient to a hospital who may be infected, as well as the need to disclose private health information to law enforcement. Disclosures to the press will be another consideration for any potential bioterrorism event, which a hospital or individual health-care provider may face. For example, the first SARS victim – a private citizen – to arrive in the United States was immediately identified in the press. Scientists and researchers, who are supported largely by government funding and through contractual arrangements, may be regulated by the federal government, but have continued for the most part to be largely self-regulated. Recent concerns about the publication of biological research which might aid terrorists in bioterrorism, sometimes referred to as the "Persephone effect," have been addressed by members of the scientific community.⁷⁶ At the Annual Meeting of the American Association for the Advancement of Science (AAAS) in February 2003, the President of the American Society for

Microbiology (ASM) released a statement from journal editors and authors which supported continued open publication of most research, but cautioned that some research if published would be likely to be used by terrorists and therefore should be withheld from publication.⁷⁷ An example of this misuse of science is that publication of data on antibiotic-resistant strains of bacteria intended to assist in the development of effective antibiotics, was instead used by former Soviet bioweaponers to develop resistant bioweapons.⁷⁸

Conclusion

The five civilian deaths in the United States due to biological terrorism signaled a new age of bioterrorism for the United States and focused attention on our concept of ethics in the conduct of warfare among nations and drove our nation and the world to consider new defenses against biological terrorism. These events raised broad new questions in biodefense ethics, merging formerly disparate areas of bioethics, international relational ethics, environmental ethics, and the ethics of war.

Examination of issues in biodefense ethics must include an approach from the perspectives of bioethics, public health, medical ethics, environmental ethics, governmental ethics, international relational ethics, and the ethics of the conduct of war. On the precipice of a world which has changed forever after September 2001, we must take on this threat of bioterrorism in the world and seek to form an international consensus in our bioethical approaches to protecting humankind.

An international dialogue might be a useful starting point, with the United States serving to initiate and host an international framework convention to begin a discussion of these issues, beginning from a deontological approach that encompasses an examination of our duties as governments to other countries, to humankind, and to the environment, and our duties as individuals and corporate entities. The warning of bioethicists that biodefense is an area which should not be ignored must be part of humankind's strategy for existence in the new post-9/11 world where the threat of bioterrorism persists.

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