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## **Bioethics and Bioterrorism\***

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A day-long conference was convened to discuss bioethical concerns arising in the wake of September 11<sup>th</sup> and the subsequent anthrax mailing incidents. As Jonathan Moreno, Director of the Center for Biomedical Ethics at the University of Virginia, observed in his opening remarks, while substantial funds have been earmarked for combating bioterrorism, none of those funds have been set aside for studying the ethical, social and legal implications of the research and practices to be developed. It was, Moreno remarked, the stated purpose of the conference to "begin the public dialogue."

The opening remarks of Arthur Caplan, Director for the Center for Bioethics at the University of Pennsylvania, echoed Moreno's concern that this developing area of bioethics not be overlooked. Caplan identified a number of what he described as "systematic and thematic issues" posed by the recent acts of bioterrorism and by U.S. efforts to combat bioterrorist threats. It was around these themes that the five panels of the conference were organized: "Biological Weapons: Threat and Response"; "Vaccination Policy and Prevention"; "Patents, Profits and Public Health"; "The Duty to Face Danger"; and "Science in the Interest of National Security."

Among the panels, some further themes emerged: a blurred line between treatment and research in emergency response care; the need for diverse public involvement in ethics dialogue; and the risk that ethics will be compromised in times of war. The following report covers the conference speakers in order of presentation.

### **Biological Weapons: Threat and Response**

#### The New Jersey Anthrax Crisis

The first speaker, Dr. Eddy Bresnitz, is a State Epidemiologist for the state of New Jersey, and was integrally involved with the state's response to the anthrax contamination incidents. Bresnitz made the point that New Jersey, as well as the nation as a whole, had been preparing for bioterrorism, albeit with minimal resources. The thinking on bioterrorism, he said, was shaped by the preparations for a pandemic influenza outbreak, which some thought would be more likely to

occur than a bioterrorism incident. Further, it shares some of the same public health concerns as bioterrorism responses. Among the common issues, Bresnitz named allocation of treatment, supplies and vaccines; coordination of response; and surveillance of outbreaks.

While prior thought had been given to public health and medical responses, Bresnitz believed that decision-makers primarily acted without any deliberate ethical analyses to guide them. The ethos, Bresnitz suggested, was one of “do the right thing.” The difficulty, he contended, was that the “right thing” changes based on the information available at the time, resulting in a “moving target.”

Bresnitz then explored anecdotally the substantial ethical questions that arose in New Jersey regarding post-exposure prophylaxis policy.<sup>[1]</sup> Bresnitz attempted, in his anecdotal overview, to give the participants a “taste of what happened in New Jersey.” The three main issues Bresnitz discussed were: treatment allocation; acting in the face of medical uncertainty; and coercion in treatment.

In terms of treatment allocation, a question arose relating to who should receive prophylactic medication. The guiding ethos, according to Bresnitz, became one of risk analysis—those at the most risk should receive the medication. A fairly straightforward approach, as long as resources aren't scarce.

Additionally, questions need to be answered concerning appropriate and effective treatment. As there were no developed civilian treatment protocols, there was uncertainty about appropriate prophylaxis, duration of medication, and best first-line medication in the event of exposure. A related issue was that the vaccine, which had previously only been available to the military, had yet to be approved by the FDA for general use. Ultimately, acting on preliminary data, New Jersey extended the period of prophylactic antibiotics to 100 days. The vaccine and antibiotic combination treatment was brought in and administered by the CDC, which gave rise to Bresnitz's third concern: coercion.

According to Bresnitz, the CDC provided the drug as part of an “investigational new drug trial,” requiring all participants to sign informed consent releases. Bresnitz suggested that the forms sought to limit the government's liability, and had a statement to the effect of ‘refusing the treatment may result in [the patient's] death’. The situation is inherently coercive, and therefore ethically problematic in Bresnitz's view.

In closing, Bresnitz observed that these issues were a fertile area for policy and ethics debate, and that while he had posed many questions, he offered few answers. In many ways, however, Bresnitz's speech was a microcosm of the core issue that would be discussed throughout the day: *bioterrorism presents problems for which we don't yet have systems of response.*

For example, Bresnitz pondered at one point, what if the disease had not been anthrax, but highly contagious smallpox? Would we be obligated to treat those exposed, potentially against their will, as a matter of public health? Would we forcibly quarantine, through use of police powers, those refusing medicines? We do have public health systems for dealing with communicable disease, but rarely do we press citizens to use experimental medications, even for the common good.

A number of audience members pointed out that there were analogous systems which addressed some of the issues presented. One example cited was emergency medicine where a treatment protocol may be used which has not been proven when the emergent condition fails to respond, or has no known treatment. Emergent conditions can also be inherently coercive, as the patient's life is often at risk. The point several audience members made, and which was echoed by speakers throughout the day, is that while we may be facing new problems, medicine, public health, and bioethics have an existing platform of relevant work on which to build.

### “Psychological Responses to Bioterrorism: It’s About Time”

The second speaker, Dr. Greg Saathoff, serves as the Executive Director of the Critical Incident Analysis Group at the University of Virginia. Saathoff sought to distinguish the critical difference between bioterrorism and other forms of terrorist attacks using more conventional “NICE weapons” (Nuclear, Incendiary, Chemical, and Explosive). Unlike NICE weapons, which are self-limiting in impact by the nature of the weapons materials themselves, bioterrorism weapons can be deployed without victims knowing they are under attack. Further, some of these weapons have the capacity to reproduce. Bioterror weapons, therefore, are not limited (or fixed) in time. Bioterror carries on, and can advance substantially before we are even aware of a problem.

Saathoff echoed the concerns of Bresnitz, stating that we do not yet have an establishment for dealing with bioterroristic infectious disease. Not only do we lack models and studies, but we already know we have “limited surge capabilities,” generally defined as the ability to provide emergency care for situations resulting in mass injuries or mass casualties. Further, vaccine availability and response protocols may be insufficient.

The psychological response to such insidious attacks, and to the fear created by them, depends on a number of factors articulated by Saathoff: leadership response; medical resources; media; law enforcement; communications; individual responses; community responses; and governmental emergency responses.

Saathoff indicated that there are seven elements to the leader’s response that would help determine the psychological response of the public. First, the leader must have clear and effective communication skills. Second, the existing level of trust in the leader at the time of the response is vitally important. (Similarly, Saathoff stated that the leader’s charisma was critical, which he defined as the leader’s ability to be trusted and be followed.) Third, the leader’s relationship with, and understanding of, the media is important. The leader must understand that the media’s critical role is not adversarial, but one which more rapidly fosters solutions. The fourth element is the leader’s previous training and experience dealing with bioterrorism. Fifth, the leader must have a thorough understanding of the interaction and availability of local, state and federal response systems. Sixth, the leader must be able to transcend partisanship and lead the entire group or entire society. And finally, the leader must be able to express what Saathoff calls “vigilant hope,” an ability to deal with the uncertainty presented by the situation and move forward.

Some of the other factors Saathoff mentioned rather briefly. The “medical resources” factor, he said, will turn on the following: experience of clinicians, especially in managing disasters and working with incomplete information; relationship of medical institutions with the government, the media and public alliances; having and using a communication network to disseminate information about the bioterrorism event; and adequate mental health resources, not just for victims, but also care providers. For the “media” factor, the critical elements are: their own leadership; the level to which the community trusts them; their bioterrorism knowledge and training; their prior experience with disasters; their relationship with medical service providers; their local and national perspective, and ability to see the relationship between the two arenas; and their ability to recognize their role as one which fills an important information void for the public. For “law enforcement”, the key elements are: prior experience with disasters; bioterrorism training; relationship with the media; and sensitivity to their own medical and other needs. For “communications,” Saathoff identified the critical elements as: the level of overlap or redundancies; prior disaster experience; and surge capability.

In closing, Saathoff remarked that although predicting the psychological response of the public to bioterrorism attacks should be sought after, the ability to do so will depend largely on the aforementioned factors.

### A Brief Response

Colonel Dr. Art Anderson, Chief of Clinical Pathology at the U.S. Army Medical Research Institute of Infectious Diseases, addressed some of the issues raised by Bresnitz and Saathoff. Col. Anderson suggested that his comments represented his own views, and not those of the Department of Defense or USAMRIID.

Anderson pointed out that the military makes top-down, scenario-driven response plans, so that when catastrophic events occur, be they bioterrorism or battle, there is an institutional protocol in place to handle the response. He added that a mechanism is needed for promoting and disseminating the military response protocols for bioterrorism incidents for the benefit of the public, something which was not done well with the anthrax exposures. One problem, Anderson noted, was that there is a stigma attached to military research because its dissemination and discussion among scientists and physicians might be restricted.

### Conference Discussion and Questions

Following the presenters' speeches, much of the discussion focused on how consent forms could be developed for an investigational trial performed in response to a terrorist incident. The general consensus among audience members and speakers was that state and local communities must be involved in all levels of planning the network of response, including such items as consent forms. Several audience members, as well as Col. Anderson, urged an open, inclusive process similar to the one currently used by local Institutional Research Boards, a process which Anderson said needed to avoid becoming "politicized."

Additionally, many were concerned by the nature of the CDC prophylaxis response to the anthrax incidents by making medication and vaccination available as an "investigational new drug trial." As Bresnitz observed, many individuals in New Jersey felt they were being experimented upon, rather than prophylactically treated. Bresnitz asserted that it might be problematic ethically, because you are acting with intent to benefit, but portraying the treatment as research, because the treatment is not yet proven or licensed. Anderson suggested that perhaps a contingency licensing scheme be developed for use in the event of emergencies.

### **Vaccination Policy and Prevention**

#### "Approaching Vaccines for Agents of Bioterrorism"

The second panel started with the comments of Dr. David Weiner, a molecular immunologist and professor in the Department of Pathology at the University of Pennsylvania, who touched briefly on the types of bioterrorist threats we might face in the future and how we might develop appropriate vaccines to reduce our risk.

Weiner noted that there were numerous agents<sup>ii[2]</sup> which could be used in a bioterrorism attack, but that recent attention had been focused on "chimeric viruses" as a possible new threat. A chimeric virus is typically created out of two or more separate viruses, for example, a combination of smallpox and the Ebola/Marburg virus. The terrorist goal could be to create a virus which would spread rapidly and that would be highly lethal.

Weiner expressed the opinion that the threat posed by chimeric viruses might not be as grave as many seemed to think. First, he pointed out that, paradoxically, chimeras may be less lethal than their counterparts are separately (or perhaps only as lethal). What makes smallpox so lethal, for example, is its lengthy incubation period (leaving hosts infectious, but not yet symptomatic), which is eliminated by a cross with fast-acting Ebola. Thus, if hosts die quickly, then the chimeric disease may not spread as well as the original smallpox. In addition, Weiner said that it was not clear that there would be a need for new vaccines, as the current multi-strain vaccines may be more effective than many assumed initially.

What is clearly needed is a vaccine strategy for containment, Weiner claims. He added that prophylaxis is typically given to confirmed cases, caregivers, hospital staff, mortuary staff, and others who have had contact with infected persons. Those at risk from vaccination itself include persons with suppressed immune systems (organ transplant recipients, cancer patients, etc.), people with autoimmune disorders, the elderly, and infants. Weiner pointed out that many of these risk groups were larger than when we last battled smallpox in the 1960's, so that the exact impact of a current vaccination campaign is harder to predict.

Weiner concluded by setting out some possible future directions. First, he mentioned the possibility of future gene-based vaccines as possibly both safer than current live vaccines, and with a stronger response than current non-live vaccines. In addition, gene-based vaccines could be very complex, so it would be difficult for bioterrorists to "engineer around" the vaccine.

### Bioterrorism and Public Health

Dr. Phillip Nieberg, Associate Director for Public Health in the Global AIDS Program at the Centers for Disease Control, followed Dr. Weiner with a macro-scale perspective of issues that might arise in respond to a bioterrorist attack. It was noted that Dr. Nieberg's remarks are his own views, and do not reflect the opinions of his employer.

Nieberg framed the issues presented by bioterrorism as public health issues, and applied a different set of ethical standards than many bioethicists, who have tended to treat bioterrorism as more of a medical issue. The ethics of public health and the ethics of biomedicine can vary, with biomedicine typically acting to protect the interests of the individual and public health acting on behalf of the state to protect the health and well-being of citizens generally. The "public" in "public health," Nieberg asserted, refers to the public decision-making process, not the intended target of the policies.

As an illustrative example, Nieberg pointed to the public health laws that mandate vaccinations for school children. From a public health view, the citizens are somewhat inconvenienced, but the health of the community is improved—even for those students who are exempted for religious reasons.<sup>iii[3]</sup> It is, he said, a classic case of the tension between a public interest and an individual one.

Nieberg gave three examples where public health concerns would likely arise, and where public health ethics might be most appropriate: rationing of medical resources; mobility restrictions; and dealing with human remains. With rationing of resources like vaccines, there are many possible metrics that could be used, he said. Some common ones are "first come, first served," "ability to pay," or a lottery. When you take into account public health concerns, other metrics may come into play, based on societal or role values: "first responders," "medical care providers," "those at highest risk," or exposed familial caregivers. A situation may arise where the government may have to take "control of health care supplies" to ensure a uniform society-wide policy, Nieberg proposed. The implied question, it seems, is when should we, as a society, have a discussion about that possibility.

The next example was that of the state using its police powers to restrict mobility to prevent or reduce exposure. The modern analogues for bioterror attack response may well be the systems for infectious disease control already in place, or those used in the not-too-distant past: isolation/quarantine; voluntary curfew; prohibition of mass gatherings; and compulsory treatment or vaccines. Again, a sharp example of balancing individual freedom with community protection—a classic public health concern.

The final example, which Nieberg briefly touched on, was that of safe disposal of human remains. Previous epidemics lead to requirements for rapid burial or embalming, even though often risk was actually fairly low. Public health here seeks to balance religious, cultural and personal beliefs with protection of the larger community.

In conclusion, Nieberg stated that all the concerns he raised require public discussion, with a transparent process for decision making and policy setting. Good communication with the public, as well as refined risk assessments when information is unavailable, will facilitate the process.

#### "Of Utmost National Urgency: Lynchburg Colony Hepatitis Study, 1942"

Dr. Paul Lombardo, director of the Law and Medicine Program at the Center for Biomedical Ethics at the University of Virginia, asked the question "do ethical touchstones change (or go out the window) during war?" An attorney and historian, Lombardo used the 1942 Lynchburg Colony Hepatitis Study as an example and cautionary note in exploring his question.

Lombardo presented the following case: in the early 1940's, the Yellow Fever Vaccine had been given to US soldiers, which resulted in an outbreak of jaundice, with one death for every 461 cases. In 1942, a study began at the Lynchburg Training School and Hospital in Lynchburg, Virginia to examine the link between the vaccine and jaundice. Researchers at the Training School injected approximately 190 children with a host of potential pathogens, including the vaccine and infected blood from jaundice patients. The research was conducted upon the institutionalized children without informed consent, and the goal was to observe the children to see if they became ill. While some of the children had permanent liver damage, none died. Ultimately, the researchers concluded, correctly, that the serum being used to produce the vaccine was contaminated with hepatitis and causing jaundice. The serum was modified, the study was published, and there was no public outcry over the treatment of these children as unwilling experimental subjects.

As Lombardo pointed out, such work was considered ethical at the time, some even invoking language to describe the children as "draftees in the war against disease." Certainly, Lombardo said, there are uncomfortable parallels to the Nazi practices roundly and rightly condemned by the world, but the Lynchburg experiment was not as malignant in its intent and purpose as the acts of the Nazis. It does, however, help to illustrate the question Lombardo asked the audience to consider: do ethical rules change to accommodate the exigencies of war?

It seems, Lombardo concluded, that we always answer the question in retrospect, rather than by proactive discussion. Public health and war are a volatile mix, he said, adding that "combining official secrecy and the fear of disease can yield ethically problematic situations."

### **Patents, Profits and Public Health**

#### Lessons from the Cipro Case

Arti Rai, a professor of law at the University of Pennsylvania Law School, sought to raise some "provocative points" about the potential effects of "breaking" pharmaceutical patents under the "Takings Clause" of the U.S. Constitution.<sup>iv[4]</sup> Under certain circumstances, the Takings Clause allows the federal government to take the property of persons (including corporations, who are an "artificial person" in the eyes of the law) by utilizing their power of eminent domain. The government is required to pay some amount of "just compensation," an amount often determined by litigation.

During the initial anthrax incidents, the Department of Health and Human Services suggested that the government might use eminent domain and the Takings Clause to "break" the patent on Cipro, a broad-spectrum antibiotic produced by the Bayer pharmaceutical company. Breaking the patent, according to Rai, would allow the government to arrange to have the drug manufactured without compensating Bayer beyond the amount determined as "just compensation." With this threat in the background, the government then negotiated a lower-than-market price for the purpose of creating a Cipro stockpile.

While the recent WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS) may preclude such takings, the federal government can and has taken patents previously, said Rai. Typically, she added, the “just compensation” was about ten percent of the monopoly sales price.

Rai is concerned that the threat of breaking a patent with the Takings Clause may have a chilling effect on pharmaceutical research and development. One alternative that has been proposed is the “voluntary buy-out,” whereby the government buys the right to manufacture the drug from the patent holder. The obvious concern is that there will be extortive pricing in the case of an emergency or disaster situation, like a bioterrorist attack.

Rai proposed a model where public funds are used for research and development, much like the government currently does with National Defense. This model seems to make particular sense in light of bioterrorism concerns, as bioterrorism touches on issues of defense and public health, Rai added.

This model, Rai suggests, would stimulate research on vaccines and antibiotics, which are not often big moneymakers for pharmaceutical companies. It would be important, she added, to evaluate closely which cases would get public funding, so as not to waste research funds.

#### Scarce Resources, Triage and Bioterrorism

Dr. James Childress, Professor of Religious Studies and Faculty Member of the Center for Biomedical Ethics at the University of Virginia, raised the question of what to do in situations of scarce medical resources, and proposed that we consider a triage<sup>v[5]</sup> model in advance. Childress referred directly to an article by Pesik, et al.<sup>vi[6]</sup> as a starting point for considering a triage model, though he made some general comments as well.

Generally, Childress said, triage models are expressly utilitarian, and thus come under attack by biomedical ethicists that tend to support more individualistic and egalitarian viewpoints. Yet, Childress argued, we do have a *prima facie* duty to maximize good within the constraints of our ethical principles. He would put forth, then, a triage model for doing so.

Childress pointed out that a frequent metric for determining who receives treatment first is those who can satisfy medical utility concerns. Obviously excluded, he continued, are constructs and categories such as ethnicity, age, gender, disabilities, antisocial behaviors, and socioeconomic status. Coupled with these distinctions are factors such as the likelihood of responding to treatment, especially to minimal treatment, if medical resources are limited.

Such a model can be constructed, Childress argues, in an ethical framework, but it must be acceptable and justifiable to the public. We must have a collective consensus, he argued, on how to treat and how to react to bioterrorism.

Childress argued that the dialogue on triage response systems must begin, and it must consider the following issues in addition to those mentioned above: justice; public cooperation, even in face of increasing illness; possibility of a weighted lottery favoring those with essential medical and social functions; and what we do when infected victims become transmission vectors, or unwitting “secondary agents of terror.”

#### Pharmaceutical Companies and Pricing

Dr. Patricia Danzon, an economist and professor at the Wharton School of Business, made some brief comments on issues regarding pharmaceutical companies, drug pricing, and patents. Economists, she said, use the criterion of “economic efficiency” to evaluate policy. Economists will favor the policy that delivers the greatest value from limited resources from the perspective of both current and future users.

Danzon argued that the pharmaceutical industry is unique, as pharmaceutical companies must spend a substantially higher amount of earnings on research and development than any other

industry. In addition, the pharmaceutical companies have a high cost to market, many research failures, a lengthy approval process for products, and like other companies, responsibilities to shareholders for return on investment. Patents, she argued, protect the pharmaceutical companies' investments, and should only be broken in rare circumstances.

One such circumstance, Danzon suggested, would be where there is a production restraint preventing access to a medication, rather than a price restraint. Her particular concern for a chilling effect is in the development end. Who, she asked, would risk money developing a vaccine, if the patent might get broken? Who should take the risk? While Danzon had no suggested model, she clearly felt that patent breaking was too heavy-handed a tactic, and that other solutions should be considered.

#### Research and Health System Efforts

Dr. William Haseltine, CEO of Human Genome Sciences, was brief but posed several questions to consider. First, he observed that the US is attempting to deal with bioterrorism threats by increasing funding to the National Institutes of Health (NIH). This, he said, means that we have turned the health system to war efforts. We should ask, Haseltine asserted, "Is this good for us?" This is a dialogue we need to have, even if we have it post facto, Haseltine argued.

He encouraged people to think through the issues involved, and not to act without careful consideration. As examples of the kinds of issues to consider, Haseltine posed the following questions:

- Should we use this effort to reinvigorate our research programs in defense?
- Should we use this effort to reinvigorate our research programs in public health?
- Should there be vaccine research for anti-biowarfare?
- What will be the reactions of universities? How will their policies affect this research?
- Should graduate students be working on biowarfare issues?

Although Haseltine did not offer solutions to these questions, he suggested that the governmental responses to these issues were overly complex and viewed governmental complexity as a barrier to solutions.

#### **The Duty to Face Danger**

An introduction given by Dr. Ann Hamric, professor of Nursing and Faculty Member of the Center for Biomedical Ethics at the University of Virginia, preceded the full presentations by the panel members. Hamric noted that the panel chose to focus on the duties of doctors and nurses, rather than all possible responders, and to conceive of the "duty to face danger" as a continuum construct.

#### HIV as a Model for Epidemic Coping

Dr. Leslie Blackhall, Director of Research at the Center for Biomedical Ethics at the University of Virginia, argued that the medical community's response to HIV disease might offer a good model for coping with epidemic illnesses, such as those which might result from a bioterrorism incident. Early reaction from medical personnel, Blackhall said, was typically overreaction: fear of contagion, reluctance to provide care, extreme precautions to avoid contact, and other unnecessary behaviors. Blackhall argued that the risk of contagion and the reasonable desire to avoid contagion are not uncommon aspects of the medical profession. There were predictions that the medical system would never be able to respond to HIV-positive patients, she said. Yet, the medical system held and began to treat HIV patients appropriately.

What led to the medical system's success in responding, Blackhall argued, was not volunteerism by physicians and medical professionals who felt it was their duty to provide care. The actions of selfless volunteers were only a part of the solution, she claimed. Blackhall identified four factors integral to the medical system finally responding in an appropriate fashion. These factors are: 1) the illness was seen as a crisis by affected communities, who organized and mobilized resources to cope, including demanding care; 2) involved institutions, including medical schools and professional organizations, created disincentives for those who refused to provide treatment; 3) incentives became available for those who did provide treatment, including funding for research and palliative treatment; and finally, 4) early predictions about high levels of contagion were groundless.<sup>vii[7]</sup>

From the HIV experience, Blackhall concluded that in order to provide adequate care, there must be: volunteer care providers, responding to a call to duty; disincentive and incentive systems, with the support of the medical establishment; an effort to reasonably protect health care providers; and a perception of opportunity for those who provide care, be it prestige, wealth, or some other reward.

#### Reconsidering the Common Law Rule of "No Duty"

Dr. Eric Feldman, professor of law at University of Pennsylvania School of Law, argued that bioterrorism concerns might lead us to reconsider the Common Law rule regarding the duty to help. According to Common Law, there is no duty to render aid or assistance to a person in need, even if one could do so with no risk to oneself.<sup>viii[8]</sup>

Feldman argued that there are a number of mechanisms that could be used to encourage health care providers to face danger by reframing the duty to care, both legally and ethically. For example, Feldman pointed out that health providers could be required to provide care in the event of an emergency through licensure requirements. In addition, while individual doctors don't have a duty to provide care, hospitals and other institutions sometimes do, particularly for emergent situations. Feldman says the current legal regime, including the requirements of the Americans with Disabilities Act, seek to protect doctors, while still encouraging them to act. The system provides "weak incentives to be a hero," he says.

So far, only the Model State Emergency Health Powers Act (MSEHPA) had systematically addressed the duty to care issue.<sup>ix[9]</sup> While the MSEHPA is not law, it does serve to offer guidance to state legislators, and may influence the types of laws and schemes enacted. MSEHPA would allow states to require health care providers to provide care in the event of emergencies, Feldman noted. The duty does vary by risk, he continued, since no one would want a scheme which would overburden health care providers.

In closing, Feldman offered five reasons why the current situation offers an opportunity to reconsider the Common Law rule. First, it is the right political climate, in light of the development of the Model Act, as well as the recent bioterrorist concerns. Second, if provision of care is only linked to bioterrorism incidents, you could end up with people who put themselves in the zone of risk to get access to other needed care. Third, reliance on the ethos of "volunteerism" will be insufficient to provide adequate care. Fourth, the hierarchy of medicine means that doctors can refuse to treat, but medical aides and nursing staff cannot, without the risk of being fired. This hierarchy results in the least empowered providers being required to face dangers that others do not have to face. And finally, the duty should be imposed to reflect the societal status and professionalism of health care providers. Feldman added that even though we would require the duty, health care providers should be given credit for acting well in the face of danger.

#### The Ethical Duty to Face Danger

Dr. Hamric presented the view that facing danger was ethically obligatory for the health care professional. This obligation, she argued, is rooted in the professional roles of physicians and nurses and in the prominent status accorded these professions. In addition, this obligation stems

from the responsibility of having increased skills and knowledge to help others, which intertwines with the duty of beneficence.

In nursing, Hamric noted, there is a strong presumption of a duty to treat, and of an altruistic duty to provide care. This presumption (really, a set of presumptions) is part of the culture of nursing, and those who refuse are informally sanctioned within the community of nurses.

Additionally, Hamric said, the presumption is reflected in both the 2001 American Nursing Association Code of Ethics and in the 1994 American Nursing Association Risk versus Responsibility Statement. Both documents encourage nurses to provide care in the face of danger, though they recognize that nurses also must be concerned with their own safety, Hamric noted. One of the difficulties nurses will face in evaluating appropriate levels of risk to self, Hamric concluded, is that bioterrorism may present situations where the risk is not known.

### Medicine and Limits

Dr. Walt Davis, the Director of Education for the Center for Biomedical Ethics at the University of Virginia, examined the “duty to face danger” as it applies to doctors. He noted that the earliest American Medical Association (AMA) codes of ethics referred to a doctor’s “responsibility to provide treatment”, but that this language was dropped from the code in the 1950s.

Following the events of September 11<sup>th</sup>, the AMA’s Council on Ethical and Judicial Affairs issued a “Declaration of Responsibility” addressing the responsibility of doctors to respond to bioterrorism.<sup>x[10]</sup> The Declaration uses an aspirational, not mandatory, form of a voluntary pledge. The Declaration used language which implies a strong duty, such as “bound,” “fulfilled this obligation,” and to “(a) pply our knowledge and skills when needed, though doing so may put us at risk.”

“Risk,” Davis noted, is undefined. It seems clear, he added, that the “duty to face danger” is context dependent, and balances the risk of harm to the provider and the potential benefits to the patient. To adequately render service and “face danger”, there is an expectation on the part of health care providers that they will have adequate information, a coherent plan, protective mechanisms in place, and that the obligations of others (such as government agencies and officials) will be met, Davis said. Davis concluded by echoing the remarks of Dr. Hamric, saying that the difficulty we currently face is that we are in a time of unprecedented uncertainty regarding possible threats and harms.

### Conference Discussion and Questions

In discussion with conference participants, there were two primary issues of concern. A number of participants were concerned about laws or regulations “forcing” health care providers to provide care. Most participants framed the issue as one of “who wants to be treated by someone who doesn’t want to treat them, and what kind of care can you expect?”

The other main issue related to which health care providers can refuse to provide care and which cannot, and what the ethical implications of that difference might be for providers, a point raised by Dr. Feldman in his talk. For example, where a doctor might be free to refuse care, a physician’s aide or orderly might not, particularly where instructed to provide said care by a doctor or nurse. The doctor might refuse without the risk of losing her job, but the situation may differ for an orderly. In addition, Dr. Hamric made the point that the doctor usually is in a position to dictate the conditions under which the care will be provided, whereas the nurse or orderly is not typically in that position. Many participants asserted that this differential authority in decision-making must be addressed for a fair and ethical response system to be developed.

## **Science in the Interest of National Security**

### "Ethics of Enrolling Vulnerable Subjects into Research"

Dr. Jason Karlawish put forth what many might cast as a contrarian viewpoint regarding research with vulnerable subjects. Karlawish, a Professor of Medicine in the Division of Geriatrics at the University of Pennsylvania, made a case for including physically frail and cognitively impaired subjects in research designed to protect us (and them) from bioterrorist incidents.

Karlawish argued that it is time for researchers to recognize that while some people are more vulnerable than others, scientists can do a vulnerable population a grave disservice by developing medicines and treatment protocols whose efficacy in treating vulnerable patients is not known. By utilizing only the healthiest subjects, no information is gathered regarding the efficacy of the experimental protocol on less healthy people.

Using a hypothetical example of a frail, cognitively impaired 75 year old woman, Karlawish asked, "Will the fruits of bioterror research be available to her?" Karlawish argued that researchers typically put the vulnerable last in line for experimental trials, but that they should be moved more towards the front.

In identifying some barriers to vulnerable people's opportunity to participate in research, Karlawish pointed out the following: the institutions which care for vulnerable persons are usually have a preponderance of low-paid staff, and are frequently understaffed besides; health issues in the frail, elderly, and other wise vulnerable person introduces experimental confounds and increases the risk to the subject; and issues of cognitive impairment obviously complicate the issue of consent (or proxy consent for which there is little to no guidance). In addition, Karlawish said, we must be able to ensure access to the "fruits of research" and find a way to monitor the trial efficacy and safety for the vulnerable population.

### Government Reorganizes to Respond

Gary Ellis is the Executive Secretary of the National Science and Technology Council, a Cabinet-level group by which the President coordinates the diverse parts of the Federal research and development enterprise as regards science and technology. It is, Ellis said, a "virtual agency" comprised of the President, Vice President, Cabinet members, and Agency heads. Since September 11th, the NSTC has been focusing on the vulnerabilities "laid bare" by the terrorist attacks.

Ellis said that Dr. John Marburger III from the Office of Science and Technology Policy had taken the lead in creating an interagency taskforce designed to address concerns about terrorism. The working groups were created focusing on chemical and biological weapon detection and response, radiological weapon detection and response, protection of vulnerable systems, and social, educational, and behavioral sciences. In addition, there is a rapid response group for emergencies.

The NTSC, Ellis said, has been planning for a systemic approach, and has received a tremendous amount of advice regarding terrorism, especially from citizens not working directly for the government. The Department of Defense, Ellis noted, has formalized the process for garnering advice, and has received over 1200 responses to a Broad Agency Announcement soliciting ideas.

The NTSC's office role is to form partnership, and is currently focusing on short-term issues, he said. The fight against terrorism "needs new tools," and the NSTC is trying to coordinate that effort, according to Ellis.

### Ethics of Research in Classified Contexts

Dr. Jonathan Moreno examined the issue of how to ethically conduct human subjects research in classified contexts for the military. He briefly reviewed some of the previous classified research where soldiers and citizens were used in experiments, sometimes with the knowledge and consent of those affected, and sometimes without valid consent.

One of the problems, Moreno asserted, is that the Food and Drug Administration is not set up to handle approving drugs for biowarfare defense. Some options have been explored, including an informed waiver process, an expedited process for “countering bioterrorism initiatives,” and a supplementary approval process based on historical experience, clinical experience, and other available information. No clear system has yet been established, according to Moreno.

The return in the U.S. to what Moreno characterized as a “Cold War stance” raises concern that an increase in classified research is likely to occur. Two items which Moreno pointed out as particularly important in this context were: 1) the granting of authority to the Department of Health and Human Services to classify information as “secret”; and 2) the government’s failure to put into place human subject research guidelines for classified research. Moreno pointed out that the federal Advisory Committee on Human Radiation Experiments, of which he was a member, had suggested some guidelines for classified research, but none had yet been adopted. Moreno expressed concern that failure to develop an ethical framework for bioterror and bioweapon research would contribute to a “legacy of mistrust” which already overshadows much of the federal government’s medical experimentation history.

#### Preparation for Bioexposure Research

For the final presentation, Dr. Caplan sought to comment and build on much of what other speakers had said before him at the conference. Caplan, who drew on his experiences with the federal Advisory Committee on Gulf War Veteran’s Illnesses, stated that the current system is not set up to undertake bioexposure research and that the system, as it is now, will not adequately protect subjects.

In the Gulf War, Caplan noted, studying the soldiers who became ill was difficult as there was no baseline health data, no rigorous assessment those soldiers who mustered out, poor or nonexistent records detailing who was exposed to which agent and in what area of the battlefield, and no sampling or analysis of the environment in which the soldiers were fighting. These hurdles to good epidemiological analyses and response planning are substantial. Data must be gathered to answer these types of questions if we are to be able to respond to bioexposure attacks, or even to environments made toxic by conventional attacks, such as the ones on the World Trade Center.

Caplan argued that we must change the way we view warfare, and we must look at the battlefield from an epidemiological view. We must be prepared to learn from disaster, he said, and have a system in place to consider the effects for five, ten, or twenty years down the road. Caplan concluded that we cannot design an experiment that will teach us how to respond to bioterrorism, but we can prepare to learn as much from natural and man-made disasters as possible, and to use that experience to prepare for the future.

#### **Commentary**

In this author’s opinion, what was particularly informative about this conference is how well it drove home the point that we are just at the beginning of a dialogue regarding the appropriate societal and medical response to bioterrorism, and the scope of the discussion to be had. This conference, and hopefully this report on it, makes clear the current need to continue the necessary dialogue in earnest. If this dialogue had been scheduled earlier, the bioethics field might have been in a better position to advise on secure research methods, attack response protocols, and other important issues. It is, of course, easier to look back and criticize in hindsight.

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<sup>[1]</sup> In passing, Bresnitz also mentioned as examples of ethically difficult areas the issues of over-prescription and hoarding of antibiotics, and the tension between self-protection and the duty to provide care. The latter issue was the subject of a panel at the conference entitled “The Duty to Face Danger.”

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<sup>ii[2]</sup> Weiner noted a “top ten” list of bioterrorism agents which he derived from a Dept. of Defense report might include the following viruses, bacteria, and toxins: Smallpox, VEE, Marburg/Ebola, Anthrax, Plague, Tularemia, Burcellosis, Q Fever, Botulism, Staphyococcal Enterotoxin B, and Ricin intoxication.

<sup>iii[3]</sup> A result of “herd immunity,” whereby the unvaccinated children are safer because there are fewer potential carriers to infect them.

<sup>iv[4]</sup> See *also*, 28 USC 1498, which governs how the Federal Government can utilize patents.

<sup>v[5]</sup> Childress uses “triage” in a narrower sense than simply resource allocation, defining it instead as a system which sorts patients in terms of needs and likely outcomes, usually in times of crisis or emergent care.

<sup>vi[6]</sup> Nicki Pesik, Mark E. Keim, Kenneth V. Iserson, “Terrorism and the Ethics of Emergency Medical Care,” *Annals of Emergency Medicine* 37:6 (June 2001): 642-646.

<sup>vii[7]</sup> Blackhall noted that this is where HIV and smallpox vary significantly. Smallpox is highly contagious and this will likely change to some extent how people respond.

<sup>viii[8]</sup> There is, however, some support for a rule which requires skilled persons or professionals not to abandon someone once they have begun giving aid or assistance to a person in need. In essence, once the delivery of help is begun, it must be seen through to a conclusion.

<sup>ix[9]</sup> The MSEHPA was developed by the Center for Law and the Public’s Health at the Johns Hopkins and Georgetown Universities. See, <http://www.publichealthlaw.net/> for the most recent version.

<sup>x[10]</sup> Issued as CEJA Report 5-I-01, American Medical Association.