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Bioterrorism and Medical Risk Management

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I. Introduction

There is little that is a certainty or distinctly “orange and blue” in the practice of medicine. What *is* certain is that most medical decisions are based on probabilities and/or risks of actions—or, very often, inactions. Likewise, when it comes to how we are going to deal with the new threats of bioterrorism, there are also no absolutes. Bioterrorism, defined as the intentional use of biological entities such as bacteria, viruses, and their toxic byproducts to cause harm to humans, animals or plants, is essentially no different in terms of the challenges of medical management.¹ Here too, in the mitigation of a bioterrorist event, as in all medical practice, the medical community will often be faced with weighing the risks of actions and inactions.

For example, being able to differentiate between “the flu” (influenza viral syndrome) and the symptoms of inhalational anthrax in its early stages is very difficult.² However, treating everyone arriving with “flu-like” symptoms at an emergency department (ED) or at a primary care provider’s office as if they had anthrax has both medical and fiscal complications.

Yet, inaction, based on the very unlikely probability that a patient presenting with typical “flu” symptoms will have anthrax, will obviously result in a high chance of a lost life if that patient does in fact have an anthrax infection. This is what happened in the index case in Boca Raton, Florida, in the fall of 2001.³ While the medical community rallied quickly and

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1. Donald A. Henderson, *The Looming Threat of Bioterrorism*, 283 SCIENCE 1279–82 (1999).

2. Thom A. Mayer et al., *Clinical Presentation of Inhalational Anthrax Following Bioterrorism Exposure*, 286 JAMA 2549–53 (2001); Luciana Borio et al., *Death Due to Bioterrorism-Related Inhalational Anthrax*, 286 JAMA 2554–59 (2001); Gina Kolata, *Anthrax Prods a Rewriting Of Medical Dogma, Quickly*, N.Y. TIMES, Oct. 31, 2001.

3. See Kolata, *supra* note 2.

prevented other loss of life after this index case, the risk is always there for the first person(s) becoming sick with anthrax. In the case of anthrax, one cannot be absolutely correct in terms of making an immediate diagnosis with our current diagnostics and the limited experience that the medical community (fortunately) has had to date with this potential bio-weapon.

Still, the practice of “covering all bets” by giving antibiotics to everyone can also be a fatal mistake. There will be people who have severe reactions to antibiotics, sometimes even fatal ones. Likewise, in the case of vaccines, deaths can occur. While smallpox vaccination is highly effective and complications are relatively uncommon, the absolute numbers of complications may be high if whole populations are vaccinated.⁴ Many healthy people can die from this vaccination (made from a live virus) and some very disabling complications can arise, particularly for those with immunologic compromise. Also, compared to forty years ago when we gained our statistical experience with complications from mass smallpox inoculations, there are now many more people living today who are theoretically at higher risk for complications. Today, there are many people infected with human immunocompromise virus (HIV) or those taking immunosuppressive drugs to treat organ transplantation, and other immune-related conditions. Therefore, public health officials will have to weigh the risks of vaccination versus “non-action” in such cases, not only as public policy, but also in terms of treating or vaccinating individual cases when a true threat exists.

These are some of the issues that the medical community and the public at large must consider in preparing for the global threats of bioterrorism. We must understand, prospectively, the likelihood of imprecise decisions so that we are not continually getting into the mode of “Monday-morning quarterbacking” and not continually trying to second-guess the medical community members who will be trying their best to cope with the evolving and relatively unfamiliar threats of bioterrorism.⁵

The rationale for having this perspective is not to elude culpability if true mistakes are made, but to diminish the complications of public misinformation and inappropriate loss of public confidence. During the intentional anthrax dispersals in the fall of 2001, there were media pundits and “would-be” experts who repeatedly “second-guessed” the public health system. Erosion of public confidence can actually lead to problems more widespread than the root problem itself. Effects on the economy, public mental health and the likes are insidious—and generally unnecessary.

Putting the 2001 anthrax “crisis” in perspective, there were many people exposed to the postal anthrax attacks, but few actually died or became significantly ill. Indeed, despite an under-resourced, and relatively under-supported public health system, the outcome was far better than one would have expected given the magnitude of the exposure and the sophistication and lethality of the bio-weapon employed.⁶

Therefore, in the following discussion, generic issues of risk management in medicine will be considered and, in turn, some of the specific risk management issues related to

4. Joel G. Breman & Donald A. Henderson, *Diagnosis and Management of Smallpox*, 346 *NEW ENG. J. MED.* 1300–08 (2002); William J. Bicknell, *The Case for Voluntary Smallpox Vaccination*, 346 *NEW ENG. J. MED.* 1–3 (2002); Jeffrey M. Drazen, *Smallpox and Bioterrorism*, 346 *NEW ENG. J. MED.* 1263 (2002).

5. See Kolata, *supra* note 2.

6. See Borio et al., *supra* note 2, at 2555; see also Morton N. Swartz, *Recognition and Management of Anthrax – An Update*, 345 *NEW ENG. J. MED.* 1–6 (Nov. 29, 2001); Gina Kolata et al., *Information on Anthrax Is Derived From Cases Mostly Outside The U.S.*, *N.Y. TIMES*, Oct. 12, 2001, at B9.

preparations for bioterrorism will be addressed and put into perspective. It is hoped that this discussion will elucidate potential opportunities that we now have and will also encourage more support for our public health system.

II. Medicine and the Art of Risk Management

Medical care is risk management. To a large extent, on a day-to-day basis, medical practitioners are risk managers. For example, in the day-to-day surgeries that they perform, or in the ED care of the sick and injured, or in dealing with these new threats of bioterrorism, there is always an inherent element of risk management.

Physicians in such settings (surgery or ED) routinely approach these situations in terms of a risk/benefit ratio. Risk/benefit is a common consideration when physicians talk to patients about specific treatment options or when the practitioner thinks about the appropriateness of performing certain diagnostic or therapeutic procedures. Even if a surgical procedure is commonplace, the surgeon still strongly considers the risks for that surgery as a finite potential, even if rare. Often, this consideration is manifested in terms of obtaining consent for surgery, generally as a hedge against subsequent malpractice claims if something goes wrong. But, in fact, long before malpractice and consent concerns, dedicated, thoughtful physicians always make risk/benefit considerations. Likewise, if academic physicians want to conduct new studies or if community physicians simply look to try some new procedures, they must consider the risks and benefits of such initiatives, be they formal investigations or otherwise. Hopefully, in most cases, the physician strives to minimize risk while maximizing benefits, but there are no guarantees against less than optimal outcomes.

Those medical practitioners most likely to help organize and care for victims of bioterrorism already deal with risk management in high profile situations such as resuscitation research and clinical care. For example, physicians specializing in resuscitation and emergency medical services (EMS) often attempt to explore new interventions, especially when, in the laboratory, those proposed therapies have been shown to have a high potential for benefit. Although there are always unanticipated risks when the investigational therapies are applied to humans, sometimes such unanticipated risks can be considered to be of negligible concern. For example, if these interventions are applied to victims of cardiac arrest (who generally have negligible chances of survival), the undetermined risks are essentially meaningless because the person is clinically dead. Therefore, the risk/benefit ratio is also negligible.

But in most other areas of medicine, "the truth is rarely pure, and never simple," as Oscar Wilde once said.⁷ For example, in general, a person involved in a motor vehicle collision may have a chance of acquiring an unstable neck injury. Although, statistically, considering all persons involved in car wrecks, the chance of having a broken neck is less than one in one hundred (low risk), the consequences of not taking actions to stabilize the neck in that rare case may be very detrimental. Specifically, the significant risk of developing permanent paralysis if there truly is a neck fracture, uncommon as it may be, begs the need for intervention (immediate spinal immobilization). Also, in this case, the interventions, such as applying a cervical collar and further immobilizing the patient's spinal column, does not

7. Quoteland, available at http://www.quoteland.com/author.asp?AUTHOR_ID=67 (last visited July 20, 2002).

involve a lot of risk. In fact, much benefit is derived if such actions can prevent the patient from becoming paralyzed.

Alternatively, physicians and public health officials might still ask if immobilizing *all* car collision patients is worth the cost. It is not always possible to rule out unstable neck injuries short of ED evaluation and diagnostic imaging. Therefore, many persons are transported to the hospital simply to rule out occult neck injury. In turn, to prevent a few paralyses, we must spend hundreds of millions of dollars annually to immobilize spines and transport hundreds of thousands patients with little (but some finite) risk of neck injury. The ethical question then arises as to whether such a policy of universal intervention is worthwhile from a societal point of view. This question is the kind of unpleasant public health policy issue that we often have to face and determine prospectively. Accordingly, there are similar implications for the new bioterrorism threats that we, as a society, now face.⁸

A. VARIABLE RISK/BENEFIT CONCERNS

In addition to relative risks and cost-benefit concerns, it must be recognized that a “right” or “wrong” medical choice depends upon the situation. For example, the average person may believe that certain thrombolytic drugs (“clot-busters”) are always good for a heart attack. But, in fact, it depends on the situation. If a man is an hour and 15 minutes into a heart attack at a small, rural facility where they have nothing to offer him except for certain clot-busting drugs (i.e., no cardiac catheterization facilities, etc.), the doctor might inform the patient as follows:

“Well, you *are* having a heart attack, but we’re not exactly sure how much of your heart muscle is involved. In general, considering all people with actual heart attacks, mild or severe, there is a ten percent chance that they will die, and a twenty to thirty percent chance that they will develop some degree of chronic heart failure. But, that means that there’s a seventy to eighty percent chance that they won’t develop the heart failure, and ninety percent chance that they won’t die. Still, I can’t tell you exactly what *your* chances are without more specialized tests – which aren’t available here. But, in general, if I give this clot-buster (a thrombolytic drug) to all heart attack patients, we may limit their chance of dying to one or two percent, or limit their chance of having heart failure to maybe ten percent. But that’s the overall statistical odds for all heart attacks. In your case, the odds may be much higher—or much lower. We can’t predict right now in this circumstance. Also, I’ve got to tell you one more thing: if you elect to receive the drug, there’s a chance that you might have a serious complication, namely a stroke – there’s only a one or two percent chance of that, but, of course, that *may* be better than the alternative of not acting at all.”

Obviously, this is a complicated scenario and a patient under the duress (and fear) of his potentially life-threatening illness may not be able to adequately comprehend the pros and cons of this circumstance. What if that man *is* the one or two percent who will have the complication of stroke, but his heart attack, in retrospect, was actually “mild”? Conversely, what if he decides to “take his chances” and declines the clot-busting therapy, only to die weeks later after developing heart failure?

In fact, the patient may look to the doctor for advice; “What would you do, doc, if you were me?” Unfortunately, in this scenario, even the doctor is unlikely to have a precise

8. Anthony S. Fauci, *Smallpox Vaccination Policy – The Need for Dialogue*, 346(17) *NEW ENG. J. MED.* 1–2 (Apr. 25, 2002).

answer because the probabilities are not clear, particularly considering the absence of specific diagnostic and therapeutic resources.

These are the kind of issues that many doctors must weigh on a daily basis. These scenarios are extremely difficult, more so than most other non-medical professional decisions, because they involve people and their lives and/or their long-term health. As in the case of the man with the heart attack, the true individual odds are unknown. Therefore, risk/benefit considerations not only depend upon the situation, but like a tornado or earthquake threat, also upon pure chance. Unfortunately, the same may be true when we consider the evolving threats of bioterrorism.

B. RISK CHANGES WITH EXPERIENCE

Another issue to keep in mind is that in medicine practitioners may come to learn that therapies, once considered lifesaving, may now be considered detrimental. At one time, advertisers for a given therapeutic intervention could say, "Control shock and save lives," and have that claim accepted.⁹ Subsequently, based on more experience with the intervention (and better data), the same intervention may be demonstrated to be detrimental as that additional information became available.¹⁰

Also, what is optimal treatment for one person might not be appropriate for another. For example, early in the fall of 2001, the media told the public that "Cipro" (a fluoroquinolone antibiotic, ciprofloxacin) was the drug of choice for anthrax.¹¹ They also implied that it took "10,000 spores" to get inhalational anthrax.¹² These claims were based on old information, scenario-specific policies or extrapolated data.¹³ Indeed, things do change. For example, the unforeseen mechanisms of the specific attacks may change the previous "rules."¹⁴ The results may even defy, exceed, or confound the expectations of the attacker(s) perpetrating the event. The events of 2001 clearly reinforced this concept. For example, we now have learned a lot more about the possible sequelae of certain anthrax dissemination techniques and, unfortunately, there are probably many other unanticipated threats that we will need to face.

Also, when dealing with terrorism, public health officials face both medical risks and political risks as well. When the threat is unfamiliar and the public is fearful, pressures may be put on political leaders to "take action."¹⁵ In addition, individuals prompted by an emotional sense of self-protection for themselves and their families, may make impulsive decisions.

As Goethe once said, "There is nothing more terrifying than ignorance in action."¹⁶ A classic example of this concept is what happened with the "Cipro underground" in October

9. Paul Pepe, *The Pneumatic Anti-Shock Garment*, PREHOSPITAL SYSTEMS AND MEDICAL OVERSIGHT (Kuehl ed., Mosby Lifeline 2002).

10. *Id.*

11. See Kolata et al., *supra* note 6; see also Tara Parker-Hope, *Surge In Use of Cipro Spurs Concern About Side Effects*, WALL ST. J., Oct. 26, 2001.

12. Parker-Hope, *supra* note 11.

13. Thomas V. Inglesby et al., *Anthrax as a Biological Weapon – Medical and Public Health Management*, 281 JAMA 1735–45 (1999).

14. See Kolata, *supra* note 2, at 2552; see also Inglesby et al., *supra* note 13, at 1738.

15. Marilyn Chase, *Americans Push for Smallpox Vaccines Despite Illness Risk, Need for Stockpile*, WALL ST. J., Nov. 6, 2001.

16. Quoteland, available at http://www.quoteland.com/author.asp?AUTHOR_ID=960 (last visited July 20, 2002).

of 2001. Many news media reported that Cipro was the “drug of choice” for anthrax based on certain military-based publications developed after the Gulf War in the early 1990s.¹⁷ As a result, many people attempted to obtain and hoard Cipro.¹⁸ Soon, Internet purchase sites for Cipro appeared. In fact, this was a problem because, in most cases, Cipro probably was not the best choice of drug (for various reasons). However, it was touted as the drug of choice in certain publications because it was considered to be the “default” therapy to give to military personnel in the event they were exposed to certain penicillin-resistant strains of anthrax that the Russians were thought to be developing many years ago.¹⁹ Military biological experts were not sure if the cheaper, less toxic penicillins (usually effective against naturally-occurring anthrax) would work against those potential anthrax strains. Therefore, it was arbitrarily decided that a new broad-spectrum antibiotic developed after the reported Russian experimentation should be used.²⁰ Cipro was a relatively new drug back at that time and considered to be a good drug to use until drug sensitivities were identified (within a day or two) after anthrax isolation.

This specific, standing military recommendation was made ten years ago when Cipro had just come on the market. Since then, other drugs have been developed as well. But, more importantly, it should be noted that, in retrospect, the anthrax used in the United States attacks in the fall of 2001 was sensitive to cheaper and safer drugs with fewer complications. With alternatives, we can avoid the potential complications that Cipro causes in children and many other problems that may occur in adults as well.²¹ As a matter of fact, many of the people who took Cipro after possible exposure in the Northeast U.S. (in fall 2001) stopped taking it within a week. Many elected to stop the medication altogether as a result of side effects. Even if Cipro was initially used (because of unknown drug sensitivities early on), the other cheaper drugs with fewer side effects could have been substituted once bacterial sensitivities were determined (a day or two after initial therapy with Cipro).

Compounding the misunderstandings about “drug of choice” were the Cipro Internet sites and hoarding phenomenon. In addition to wasted expenditures for the individuals involved, there also was a potential threat that many people, who might actually need Cipro, might not be able to obtain it if supplies were being stockpiled by unexposed, but worried, individuals.²² There is also the concern that, if many people start taking this drug empirically and randomly, this could lead to the development of Cipro-resistant bacteria, a common mutational phenomenon that can occur with certain antibiotics that are used widely. Therefore, these considerations have major implications for all of us as a society and they deserve to be addressed in our risk management of bioterrorism. Interestingly, there are now government lawsuits levied against the Cipro Web sites. The attorney generals of Washington State and Florida partnered in a lawsuit against the administrators of these Internet sites as well as the doctors who were responsible for this inappropriate prescription technique.

Nevertheless, the “mis-information super-highway” seemingly opened into a 10-lane interstate during the fall of 2001. Almost daily, another anthrax pundit promulgated a new public scare; “the sound-bite *du jour*” as many of us called it. As stated previously, during

17. Inglesby et al., *supra* note 13, at 1737.

18. Parker-Hope, *supra* note 11.

19. Inglesby et al., *supra* note 13, at 1742.

20. *Id.*

21. Parker-Hope, *supra* note 11.

22. *Id.*

the anthrax scare of 2001, the media reported, "It takes eight-to-ten thousand spores to cause inhalation anthrax."²³ But what does that mean to members of the public – are they now safer – less safe? How much *is* ten thousand spores? In essence, that extrapolated information comes, in part, from primate experiments that, in essence, showed that the "LD50" for the animals in a basic experimental setting, was about 2,500 to 55,000 spores.²⁴ LD50 means that the lethal dose in 50 percent of the animals probably averaged about ten thousand spores. In reality, we all want to know the LD1. In other words, what level of exposure is enough to kill anybody? So that media sound-bite *du jour* was rather meaningless for the public. After all, physically-speaking, 10,000 spores is no more than a speck of dust.

The public also heard that anthrax was "ninety percent" fatal. Some even qualified that *inhalational* anthrax was 90 percent fatal. But where did these "facts" come from? It is believed that most persons quoting this statistic are referring to the inadvertent anthrax aerosol exposure in Russia during the 1970s in which approximately 90 percent allegedly died (Boris Yeltsin opened up a retrospective investigation in the 1990s regarding this previously unreported event).²⁵ However, it is believed that many of the persons falling ill were elderly people and most of them were smokers. At the same time, it is also believed that thousands of people were probably exposed to the anthrax cloud and that consideration should be kept in perspective as well. Also, the Russians in that area did not have access to the kind of diagnostics and therapies that we have in the U.S. today, so a 90 percent death rate may be an overly pessimistic prognosis. Nevertheless, *any* rate of death is still of concern.

It has been reported that Goethe once said, "When facts are scarce, words soon take their place."²⁶ Many people criticized officials of the U.S. Public Health system and Secretary of Health and Human Services, Tommy Thompson, for their initial approaches to the anthrax problem in the fall of 2001. However, those officials were making decisions and making assumptions based on material that had been recently published (1998–1999) and these publications were based on the best available knowledge at the time. We have learned much about anthrax since then and are being more careful about accepting prior assumptions now. To our knowledge, no one *in any country* had ever had an exposure similar to the U.S. postal system anthrax attacks of 2001 and never with the kind of weapons-grade agent that was used here. Relatively speaking, the anthrax attack of 2001 was handled very well. Reportedly, the medical community in Boca Raton, Florida, where the first anthrax case appeared, had not undergone as much of the typical anti-terrorist training seen in many other major urban centers. While the first man identified with anthrax died, local medical authorities rapidly and accurately diagnosed the problem and treated all of the other people possibly exposed, even though this was a new challenge to them.

Nevertheless, as more and more high profile people became exposed, the situation became more and more political and there was pressure to treat everybody with antibiotics. Again, putting the 2001 anthrax attacks into perspective, a dozen people died but thousands of people were exposed. To some extent, there was a lot of "overkill"—much of it due to

23. See Kolata et al., *supra* note 6.

24. Inglesby et al., *supra* note 13, at 1742.

25. Matthew Meselson, *The Sverdlovsk Anthrax Outbreak of 1979*, SCIENCE 1202–8 (Nov. 18, 1994), at <http://www.pbs.org/wgbh/pages/frontline/shows/plague/sverdlovsk> (last visited July 20, 2002).

26. Quoteland, *available at* http://www.quoteland.com/author.asp?AUTHOR_ID=404 (last visited July 20, 2002).

political pressure, not medical appropriateness—to treat many people with antibiotics, though their risk was low. In essence, the risk management of bioterrorism may not be purely medical risk management.

Ironically, if an earthquake happens or a killer hurricane occurs, there seems to be a general resolve that a certain number of lives will be lost. It is almost an expectation that there is going to be a certain number of deaths and injuries despite development of reinforced building codes, early warning systems, and other governmental interventions. No government can completely protect its entire population from all evils. It can only hope to minimize the risks. It is not good if one person dies but still one must keep in mind that there is going to be some risk of death when it comes to an unexpected attack. Public safety and public health officials will do their best to prevent such occurrences, to maintain vigilance, and to uphold appropriate surveillance. Still, this does not mean that physicians should treat everyone with flu-like symptoms with antibiotics unless there are additional pieces of evidence. Bioterrorism, like all other medical conditions, including early heart attack and stroke, is a risk that, with preventive measures, can be dramatically decreased, but not entirely eliminated. Keep in mind that, according to the latest statistics, on any given weekend, more than 100 people will die prematurely on the nation's roadways because of drunk drivers and more than another 200 will die unnecessarily because their loved ones had not bothered to learn the very basic skill of cardiopulmonary resuscitation (CPR).²⁷ In other words, each week, year after year, hundreds of Americans die prematurely and unnecessarily. Perhaps we all should ask, "Where is the political pressure for those cases of medical risk management?"

III. Threats to Globalization As Well As Day-to-Day Medical Care

In the medical community there is concern that there may be less globalization as a result of bioterrorism. There are various international standards for medical practice that are continually in development. But such initiatives may now be compromised. Fewer medical experts may travel to different countries to work on such consensus processes. In addition, there may be less international collaboration on research. This will have negative effects on public health because it could put us behind in terms of scientific advances.

Another problem that the medical community faces in terms of preparing for weapons of mass effect (WME) is that there is going to be a further drain of resources for the already stressed U.S. healthcare system. There will be a certain degree of prioritization of the federal budget for anti-terrorism projects and, more than likely, money will be disproportionately targeted for military and law enforcement needs. In turn, monies may be directed away from healthcare needs including clinical care, medical education, and scientific research. Also, there will be an increasing amount of "non-productive time" for many in healthcare as their time is being consumed more and more in terms of preparing for bioterrorism and other security issues. Instead of being focused primarily on clinical care, education, and research many healthcare practitioners' time will be further diluted by anti-terrorism planning meetings, policy development, specialized education, and related training.

27. Paul Pepe, *Clinical Update: Ensuring the chain of survival in our community*, 87 DALLAS MED. J. 290-3 (2001).

A. THE RISKS OF DILUTING MEDICAL FOCUS

In some academic centers, the time spent on anti-terrorism activities is now consuming administrative and training time that would be comparable to the full-time equivalent (FTE) efforts of several faculty members. This time is spent participating on an increasing number of panels and committees to do more and more planning for the possibility of terrorist strikes. From internal policy development and evaluation of internal capabilities to community and regional liaisons, many medical professionals are compelled to participate in working relations with law enforcement, emergency operations centers, regional health departments, political leaders, other physicians, and hospital representatives. Then, there are all of the additional training obligations, whether it is for medical students, physician colleagues, nurses, laboratory workers, and many others including the public at large.

While healthcare agencies and emergency planners may all agree with these activities, who will be willing to pay for this expenditure of time and effort? Physician salaries are relatively high and, classically, physician time is paid for through clinical services. But this dilution of time detracts from clinical service (which generates patient fees), educational activities (often paid in part through tuitions), or research time (often paid through related grants). Perhaps anti-terrorism monies need to take into account the critical need for this expertise and the time that it takes to provide it.

B. PLANNING FOR BIOTERRORISM RISK MANAGEMENT

The threat of bioterrorism imposes special risk management challenges that medical providers must address. For example, as previously mentioned, in the case of smallpox vaccination, there is risk/benefit challenge that we now face for what is really a "theoretical risk." The reason that smallpox is being called a theoretical risk is that the public health community eradicated the disease from the face of the earth by the late 1970s. However, cultures of the virus were maintained in two laboratories, one being at the Centers for Disease Control (CDC) and the other at the Vector laboratory in Russia.²⁸ It is generally considered that the CDC stores are (and have been) safe, but many bioterrorism experts believe that we cannot be entirely sure about the safety and security of the Russian cultures. Indeed, many authorities believe that several terrorist nations have hidden smallpox cultures and that many may even have weapon-grade forms of smallpox. Therefore, this could still be considered a theoretical risk, so for now, public health officials are aggressively preparing for this potential threat.

Likewise, it is generally believed that our domestic (CDC) laboratory cultures are secure; however, there is a possibility that the anthrax attacks of 2001 were domestic in origin. Thus, it is possible that there are those in our own country with laboratory expertise who may be willing to harm their fellow citizens.

While the medical community may therefore want to prepare for a smallpox attack, should it do so by vaccinating all Americans now?²⁹ It must be recognized that the smallpox inoculation is derived from a live virus (vaccinia). If given to a person with HIV infection or any other immunological compromise, there is a risk that such individuals may die from

28. Fauci, *supra* note 8, at 2.

29. See Breman & Henderson, *supra* note 4, at 1304; *see also* Bicknell, *supra* note 4, at 2; Drazen, *supra* note 4, at 1263; Fauci, *supra* note 8, at 2.

an overwhelming infection from the inoculation virus. In addition, though rare, on any given day, many "normal" individuals receiving the vaccination could develop complications from the live virus inoculation. At the current time, without further proof of a threat, our national public health policy is not to vaccinate everyone. However, there are those that believe that if we are ever attacked, thousands may die and based on prior statistics of complications, universal vaccination of all Americans would only lead to a couple hundred deaths.³⁰ In addition to the concept of "theoretical risk," the counterarguments to this proposition are that there are many more immunocompromised persons alive today and that there are also many more complications that can occur especially in persons with underlying skin diseases.³¹ Thus, the risk management decisions here are difficult in terms of public health policy. What if we are attacked and many people die? Should we blame the current public health leaders or simply recognize that they used their best judgment given the most up-to-date medical and intelligence information?³²

Also, if we do have a true smallpox outbreak, we may need to vaccinate thousands of people en masse in a given region. We would first need to vaccinate the medical personnel providing the inoculations as well as their family members. But if the family member (or any other exposed person) has eczema, has an asthma attack that has been treated with large doses of steroids, or has a transplant that has been treated with immunosuppressive drugs, current protocols might exclude such persons from vaccination. If so, how would a person terrified of the smallpox attack react to this exclusion? Also, if we deny vaccination for such patients, are there civil rights issues that must be prospectively considered? If an immunosuppressed person says, "O.K.—but I still want to be vaccinated and I'll sign a waiver," and public health officials do so, are they still liable if the vaccinee then gets sick (or even dies)? Or what if public health officials simply say, "We can't vaccinate you," and then the immunocompromised person does develop smallpox? What then? Should these issues be decided through development of prospective criteria or perhaps legislated indemnification? While the process may be difficult, one should then consider the difficulties and perceived inequities involved in a retrospective decision-making process. Clearly, if at all possible, medical providers, legislators and other legal minds must attempt to define public policy in a prospective fashion.

Other legal considerations include the problem of "right to public assembly" or "freedom of movement" when quarantines are imposed to halt the spread of a highly communicable infectious disease. Other issues involve individuals' "right to privacy" when the sharing of infectious disease exposure information could be of benefit to the public. Other risk management issues include the need to modify current rules and regulations regarding patient transfers in public emergencies as well as the use of "civilian" volunteers in a mass exposure situation. All of these considerations should be examined prospectively to establish appropriate policies or modified regulations.

Then again, if we do establish prospective rules, should we also provide for flexibility in them as we learn more about the biological threat and the true risk of the vaccination and other prophylaxis in modern day America?

30. See Breman & Henderson, *supra* note 4.

31. Fauci, *supra* note 8, at 2.

32. *Id.*

IV. Some Positive Opportunities in the New Era of Bioterrorist Threats

“So if life hands you those lemons, make lemonade.”³³ Despite the terrible new threats, there are opportunities now to improve our public health system. If we improve laboratories and surveillance systems for bioterrorist threats, we would also be improving medical care for other public health threats such as food borne epidemics, influenza, and perhaps other heretofore unforeseen infectious diseases (e.g., HIV in the early 1980s, West Nile Virus in the 1990s). In other words, if we improve our surveillance mechanisms and public health laboratories, it would not only assist with the mitigation of a bioterrorism event, but also help to improve day-to-day healthcare in the United States. In many municipalities, our public health system has been ignored and often left to languish. Therefore, the current milieu provides an opportunity to improve our systems of public health overall. We may also improve vaccine research by prioritizing this area of research. In fact, we may be able to produce vaccines that will not only eliminate certain infectious diseases, but even prevent some types of cancers as well.

The current terrorist threats may also prompt us to improve hospital infrastructures and related services, including security and capacity issues. We may also prepare for other disaster situations (e.g., floods, hurricanes, earthquakes, tornadoes) by improving emergency communications systems or by cross-credentialing hospital personnel so that, in case of emergency, they may go to work at another healthcare facility if necessary (e.g., when their own facility is incapacitated). It must be recognized that hospitals themselves may be terrorist targets. By establishing prospective plans that allow personnel to work at other locations, medical care in disaster situations may be facilitated and risks to the population diminished.

Other plans can be put into place such as developing advanced disaster life support (ADLS) courses and other advanced training for EMS personnel. For example, EMS personnel may be trained to provide medical support such as mass vaccinations and other prophylaxis if necessary. Such training may be helpful in terms of facilitating other community-wide prophylaxis programs such as influenza vaccinations. Likewise, hospitals may partner to purchase mass quantities of vaccines and antibiotics as a consortium, allowing those facilities to lower the costs through economies of scale and even provide strategic coordination. For example, the consortium may stagger shipments of drug batches, so that drug expirations will be sequential and not simultaneous. This will lead to longer shelf lives and minimize waste. Such cooperation could be extended to other areas of medical care as well, and perhaps such activities may maximize efficiencies and efficacies on a day-to-day basis.

Also, we have an opportunity to organize the media. Based on lessons learned in the fall of 2001, we know that the media can be critical barriers in the effort to get authoritative and appropriate communications across to the public. We may now partner with the media for the public good and to help maintain accurate information and public confidence when a major event occurs. In essence, having the media prospectively educated and informed may diminish the risk management threats that emanate from “second-guessing” and “Monday-morning quarterbacking.” While the specifics of classified information need not be disclosed (such as the location of antidote and antibiotic caches or sites of back-up

33. Quoteland, available at http://www.quoteland.com/author.asp?AUTHOR_ID=404 (last visited July 20, 2002).

communications systems and medical care facilities), high-level members of the media (e.g., news directors) can be educated about the conceptual framework for the expected plan of action. Prospective scripts of information can be developed in conjunction with the media, using their expertise. Such education and empowerment may help to facilitate appropriate communications at the time of a public health emergency and hopefully diminish the risks of misinformation dissemination. After all, medical risk management is, in great part, achieved through medical education.

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