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Thanks Dana for your
input -

✓ Drew B

BETAC CORPORATION

March 29, 1993

Mr. John H. Gibbons
Director of the Office of Science and Technology
Assistant to the President for Science and Technology
Old Executive Office Building
17th Street and Pennsylvania Ave, NW
Washington, D.C. 20500

Dear Dr. Gibbons:

You may recall that I worked on the Chemical Biological Subcommittee with Josh Lederberg on the OTA report on Technology Against Terrorism.

As you know, we have a serious national problem in terms of protection against biological terrorist incidents. Your committee and other authorities consider the initiation of such incidents with massive loss of life and devastating political fallout only a matter of time.

There are numerous authorities outside of the Government concerned about this problem who have been attempting to get some effective Government action for a considerable period.

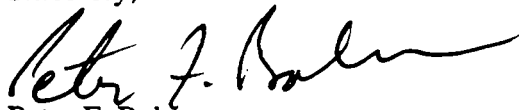
We have discussed this problem with knowledgeable Congressional parties over the years and with Tony Fainberg. We do not believe that the problem is on the way to resolution and lots of us are going to be held accountable after the fact.

We believe there is a politically supportable way to accomplish this under the environmental rubric and with the additional effect of adding to our capability to deal with hazardous materials in a much more effective manner. A program which both defense mavens and greens can support is already lying there ready to pick up.

A person from the Office of Emergency Services from California and I would like 15 minutes of your time to explain how this might be done. It could be an interesting and effective way to convert swords into plowshares and the funds can be squeezed from current allocations.

Ms. Bradford is in town this week. If you could spare fifteen minutes, it could be vitally important to the lives of people in this country. Josh Lederberg or Tony Fainberg can attest to my bone fides if necessary.

Sincerely,



Peter F. Bahnsen
Senior Vice President

Janet K. Bradford:

Ms. Bradford is the Chief of Program Development, Research, and Administration for the California Specialized Training Institute and also the Senior Emergency Management Coordinator for the Governor's Office of Emergency Services. Ms. Bradford has lead California's efforts in emergency hazards and developing liaisons and new technology for environmental management. She has been an active researcher, educator, and disaster responder at the international level for over 15 years.

Dr. Chris Hatcher:

Dr. Hatcher is a clinical professor of psychology at the University of California, San Francisco, and Director of the Center for the Study of Trauma. Dr. Hatcher has been involved in international anti-terrorist operations for over 20 years. He is frequently consulted by Federal Agencies and Corporations sensitive to issues in this area.

Dr. Raymond A. Zilinskas:

Dr. Zilinskas is an associate research professor at the Center for Public Issues in Biotechnology at the Maryland Biotechnology Institute. He has consulted the United Nations in the area of proliferation of biotechnology in countries on the verge of developing weapons of mass destruction. He recently sponsored a national conference of microbiology researcher centering on the issue of voluntary research standards.

Dr. Stanely Wiener:

Dr. Wiener is a professor of internal medicine at the University of Illinois Medical College at Chicago. Dr. Wiener has more than 30 years of Government experience in addressing biological hazards and biological terrorism/warfare. He is a member of the OTA Panel on Terrorism Issues.

Clinton R. Van Zandt:

Mr. Van Zandt is a supervising special agent at the Federal Bureau of Investigation Academy's National Center for the Analysis of Violent Crime. Mr. Van Zandt is a leading agent in the development of protocols and standards in training for sensitive FBI investigations of nuclear, biological, and chemical terrorists.

Peter F. Bahnsen:

Mr. Bahnsen is currently the Senior Vice President of Business Technology and Development at the Betac Corporation. He is a former professional senior level official in the Office of the Secretary of Defense. He created the technical support working group (an interagency R&D group which supports a myriad of counter-terrorist R&D projects) and directed all special operations R&D and Funding for Defense for over five years. He is also a member on the OTA on Counter-Terrorism Issues.

William M. Medigovich:

Mr. Medigovich is the Regional Director of the Federal Emergency Management Agency's Region IX. He has been active for over 30 years in military intelligence work and has served as the Director of the Governors' Office of Environmental Studies in California. He is responsible the governing Federal responses to national and technical hazards in 5 states and the Pacific Trust Territories.

Topics for Discussion

I. Biological Hazards are a growing national problem.

A. Terrorism

1. OTA Report.
2. Congress: Browder & Glenn Committee.
(Testimony by CIA Director Woolsey.)

B. Disease: AIDS.

C. Bio-Engineering.

1. VP Gore's Biotech initiative.
2. No to stifle R&D, but develop prudent precautions as we go.

II. The ability to respond to biological hazards and natural disasters should both be addressed jointly.

A. FEMA problems with Hurricanes Hugo, Andrew, and Iniki.

Interaction between DoD and FEMA needs definition and strengthening.

III. This is an opportunity to address both issues and create an appropriate organizational vehicle to coordinate a "national response."

A. "New FEMA": James Witte, Lacy Suiter, and Bill Medigovich.

B. "New DoD Thrust": Sixth Army, Plowshares, and House Armed Services Committee support, and major defense efforts.

IV. Build upon existing programs for disaster response: Federal Response Plan and California Emergency Plan; HazMat/Chemical Emergency Preparedness.

V. This is an environmental issue which will also take care of national security needs.

A. This will allow us to address the contingency of biological terrorism without creating the incident we're trying to avoid.

VI. Now is the time.

A. California is ready.

1. Easy target: Diverse population; unregistered immigrants; concentration of biotech industries.
2. Most sophisticated emergency management organization.
3. Best coordinated with FEMA: Federal Response Plan was developed for California.
4. Existing superior relationship with the FBI.

- C. Congress.
- D. DoD is ready.
- E. FEMA can be ready.

VII. What needs to be done.

- A. Small national working group (lean and mean).
- B. Initial focus on decision support systems and decision aids.
- C. Expansion of military program in vacancies and medical support capabilities.
- D. Begin model program in the State of California.
 - 1. Planning.
 - 2. Training and simulations.
 - 3. Response teams.
 - 4. Specialized equipment development that supports both biological disaster relief and HazMat spills.

VIII. Funding.

- A. Reallocation of current funds from FEMA Civil Defense, Defense Chemical/Biological. Redirection of DARPA (ARPA) funds are already allocated (no new money).
- B. Proper planning saves money on response.
- C. Reallocation of civil defense positions.

Follow-Up:

- Dr. Chris Hatcher will be meeting with the President on terrorism, etc. when the Waco incident is over. (Hatcher worked with the President on Russelville, Sheridan, and other Arkansas incidents.)
- We will meet with Congress as required to advance White House agenda to advance this effort.
- Need to set-up follow up meeting with Dr. Johns or Dr. Gibbons prior to Dr. Hatcher meeting with the President.

BOTTOM-LINE: We can help you make it happen.

- Off-Line information collection.
- Off-Line Plan Development and Support.
- Off-Line Jaw Boning.

02 April 1992

BETAC CORPORATION

2001 N. BEAUREGARD ST. • ALEXANDRIA, VIRGINIA 22311
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FAX (703) 824-0333

1. Letter to Dr. John H. Gibbons
2. Topics for Discussion
3. Biological Hazards and Emergency Management
4. Technology Against Terrorism; The Federal Effort
5. Bibliographies

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LETTER TO DR. GIBBONS

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BETAC CORPORATION

April 2, 1993

Dr. John H. Gibbons
Director of the Office of Science and Technology
Assistant to the President for Science and Technology
Old Executive Office Building
17th Street and Pennsylvania Ave, NW
Washington, D.C. 20500

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DISCUSSION TOPICS

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Divider Title: Bio Hazards & Emer. Mgmt

**BIOLOGICAL HAZARDS
AND
EMERGENCY MANAGEMENT**

**Janet K. Bradford, Chris Hatcher, Raymond A. Zilinskas,
Stanley Wiener, M.D., Clinton R. Van Zandt,
Peter F. Bahnsen, and William M. Medigovich**

March 1993

Working Paper #82

**Natural Hazards Research and Applications Information Center
Institute of Behavioral Science
University of Colorado**

Janet K. Bradford is the Chief of Program Development, Research and Administration, for the California Specialized Training Institute, and also Senior Emergency Management Coordinator for the Governor's Office of Emergency Services.

Chris Hatcher is Clinical Professor of Psychology at the University of California, San Francisco, and Director of the Center for the Study of Trauma.

Raymond A. Zilinskas is Associate Research Professor, Center for Public Issues in Biotechnology, at the Maryland Biotechnology Institute.

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Peter F. Bahnsen is Senior Vice President, Business and Technology Development, of BETAK Corporation.

William M. Medigovich is the Regional Director of the Federal Emergency Management Agency's Region IX.

The viewpoints expressed in this paper are those of the authors, and do not necessarily represent those of their affiliated agencies.

PREFACE

This paper is one of a series on research in progress in the field of human adjustments to natural hazards. The Natural Hazards Working Paper Series is intended to aid the rapid distribution of research findings and information. Publication in the series is open to all hazards researchers and does not preclude more formal publication. Indeed, reader response to a publication in this series can be used to improve papers for submission to journal or book publishers.

Orders for copies of these papers and correspondence regarding the series should be directed to the Natural Hazards Center at the address below. A standing subscription to the Working Paper series is available. Papers cost \$3.00 on a subscription basis, or \$4.50 when ordered singly. Copies sent beyond North America cost an additional \$1.00.

The Natural Hazards Research and Applications
Information Center
Institute of Behavioral Science #6
Campus Box 482
University of Colorado
Boulder, Colorado 80309-0482

SUMMARY

Throughout history, every promising new technology has brought new risks along with it. This paper describes two types of biological hazards: those that are naturally occurring and those that are the result of the development of biotechnology. Human safety may be endangered by biological hazards as a result of accidents in laboratories, transportation accidents, natural hazards, deliberate misuse of technology, or changes in global ecology. Public policy makers and the constituents to whom they report characteristically turn to emergency management professionals when such issues materialize in their communities. In order to cope with this new risk, the emergency management community must identify potential problems, develop response plans, mitigate hazards where possible, and ensure the preparedness not only of government agencies but also individual citizens.

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BIOLOGICAL HAZARDS AND EMERGENCY MANAGEMENT

INTRODUCTION

Responding to disease outbreaks was one of the first tasks of early emergency managers, and even primitive cultures developed strategies to isolate contagious individuals to protect the community. Today, additional biological problems are possible. Large quantities of hazardous biological agents and substances are produced throughout the United States every day, in clinical and research laboratories where pathogens are cultured and in industrial facilities producing toxins and vaccines for commercial purposes. While by far most of this work is routine, posing no unusual hazards to workers or the public, accidents or other special circumstances can at times transform the routine into peril. "It is a simple truth that technology develops faster and further than policy," Vice President Al Gore recently wrote. "Biotechnology is developing faster than any previous technology, and in the process creating a wider gap between practice and policy" (Gore, 1991, p. 19).

One policy area which needs increased attention is how our society will approach a biological hazards emergency. Even with the best safety plans and protocols, product failure, such as seal breakages will occur; transportation accidents are possible; and human error is inevitable.

For example, on December 28, 1990, four maintenance workers at a Berkeley, California pharmaceutical factory came frighteningly close to spreading bubonic plague among that city's 105,000 inhabitants. On that day, the workers did something they were not supposed to do: they entered Building Forty-Six. Building Forty-Six was where the company cultured over two million doses of vaccine a year of *Yersinia pestis*, the bacterium that causes bubonic plague. The fact that the tragedy did not occur was due simply to chance. What neither the workers, the nurse on site, nor the physicians to whom the men were sent knew, was that vaccine production had ceased a few days before entry and that the building had been decontaminated. As far as they were concerned, the workers had been exposed to plague, so the very real question was what to do about it (Winokur, 1991).

Although a release of *Yersinia pestis* in the air would be quite serious, the release of other readily available agents could be catastrophic. In the United States, an intentional aerosol release of anthrax in an urban area would result in thousands of deaths. Even if antibiotics were available in substantial quantities onsite, the death rate would be close to 100%.

Incidents such as the one described above pose two, somewhat clashing issues.

1) There was a very real potential for loss of life through several possible safety hazards. Community members and government officials were concerned about the possibilities of (a) product failure in the containment environment; (b) a structural failure due to an external natural hazard, such as an earthquake; (c) problems from procedural violations, such as the one described above; (d) an intentional release by vandalism; or (e) an intentional or accidental release as a result of theft or criminal or terrorist elements.

2) On the other hand, the pharmaceutical company is one of the city's leading employers, with a work force of over 600 people. At the time of this incident, the company had an application before the city council for a 30-year agreement that would allow it to make its operation a center for the development and manufacture of products based on emerging new biotechnology. It planned to add 50% more employees, and increase tax revenues to the city by about \$2 million a year. An imposed ban or stricter controls could discourage the company from expanding its operation or induce it to move elsewhere.

Biotechnology is a key to future industrial productivity in America. However, just as chemicals have allowed great economic and technical advantages while requiring significant new responsibilities toward the public welfare, so must the development in biological industry be accompanied by protective measures and policies. While emergency services professionals have yet to face biohazards as routine response issues, avenues exist based on prior hazardous materials experience for the improvement of both short-term and long-term response plans for this hazard.

This paper will discuss and analyze the two general types of biological hazards; i.e., those whose etiology is nature and those which are the result of human activity. The first type has, in the past, been considered a public health concern, and addressed by public health workers, especially infectious disease experts. The section on the second type of hazard, that resulting from the development of biotechnology, opens with a background on the development of biotechnology, including its putative risks and responses to those risks. Biological hazards that may result from accidents in laboratories, or be brought about deliberately are discussed, and the paper closes with recommendations on how policy makers and emergency managers should improve preparedness to meet biological threats.

NATURAL BIOLOGICAL HAZARDS

In general, natural biological hazards are infectious diseases or diseases caused by toxins produced by microorganisms. They recur throughout history: Thucydides described a plague epidemic in Athens

over 2000 years ago. Bocaccio observed 650 years ago that during the Great Plague, which wiped out over a quarter of the people in Europe, half of the population fled, and the other half, thinking their lifetimes had suddenly been curtailed—as they were about to be—spent their remaining weeks in drunkenness, orgies, crime, and violence (Clarke, 1968). An influenza outbreak during the winter of 1918-19 killed over 20 million people, and as recently as 1973, an outbreak of cholera resulted in riots when limited amounts of vaccine were made available ("Cholera . . . ," 1973). The present AIDS pandemic likely will kill many millions before it is brought under control.

Changes in global ecology are presenting new hazards. Increasing interdependence and worldwide interactions provide new opportunities for natural biological processes to affect societies. For example, in 1976 a new subtype of the ebola virus, *Ebola Zaire*, emerged simultaneously in 55 villages near the Ebola River, killing 88% of the people it infected. Its close cousin, the *Marburg* virus, caused the death of thousands in the Sudan in 1967, and, transmitted by monkeys imported to Germany for medical research, also killed 31 laboratory employees. Then, in 1989, another variety of ebola, now called *Ebola Restin*, was discovered in research monkeys in a private laboratory near Washington, D.C. Analysis and rapid intervention by the U.S. Army Medical Research Institute for Infectious Diseases led to the destruction of over 700 monkeys, and the commercial office building in which they were housed remains sealed today (Preston, 1992).

Ebola is not the only virus coming out of the rain forests. The emergence of the HIV virus, causing AIDS in humans, may also be a natural consequence of increased human movement into the tropical biosphere. By far, most of the pathogenic viral species on this planet live in or originate from the rain forests. As humans encroach on these forests, we interact with new organisms. When an ecosystem suffers damage, many species die out, but a few find a new ecological niche. The HIV virus, having found a new niche, seems to be a successful species—and it may be an indicator of other virulent viruses that could emerge in the future. Future disease agents, however, will exert their effects in different, unpredictable ways.

High speed air travel provides a new vehicle for viruses as well as people. For example, a person may contract a virulent disease agent in Africa, board an airplane, travel to the United States, and reach his or her destination while the disease is incubating, without showing indications of its presence; then come down with acute symptoms at home. In some cases, while traveling, this victim could have unknowingly spread the pathogen via touch or aerosol to hundreds of nearby people.

Of course, biological agents and toxins threaten more than just people. Recently, emergency management personnel in the United Kingdom assisted in ameliorating the worst effects of the so-called

"mad cow disease," which resulted in the forced slaughter of tens of thousands of cattle and other animals. If this scourge, whose causative virus has not yet been identified, were to appear in the continental United States, emergency management personnel would be requested to assist agricultural specialists in controlling it. Other animal diseases may be even more damaging. For example, if foot-and-mouth disease were to reappear in North America, an immediate emergency response would be necessary in order to prevent a loss of hundreds of millions of dollars by U.S. agriculture. A catastrophic outbreak of an extremely damaging plant disease might also require an emergency management response.

While disease and contamination so far have been addressed primarily through public health channels, it is evident that emergency managers will need to become increasingly involved in biological hazard outbreaks, which may affect hundreds or thousands of people in a very short time and whose origin and effects may not be immediately apparent.

HUMAN-CREATED BIOLOGICAL HAZARDS

The potential for biological hazards whose lethality and speed of movement will require greater teamwork between the medical community, public policy makers, and emergency managers is increasing as newer technological developments in bioengineering pose significant new challenges. Since 1973, when the first genetic engineering technique of recombinant DNA was developed, the number of companies that conduct research using these techniques in the United States and throughout the industrialized world has increased dramatically. At this time, thousands of laboratories and hundreds of industrial firms in the United States use biotechnological techniques, in projects ranging from agriculture and medicine to the environment and energy. The likely benefits to society are important, including fresh foods with longer shelf-lives, new therapeutic medicines, safe efficacious vaccines, new approaches for overcoming genetically-linked diseases in humans, new biodegradable materials, and so forth. The commercial value of these inventions is potentially great, making bioindustry appealing to investors. However, with thousands of people now working with, or near, biological agents, the risk of accidental release affecting workers and the general public is ever-present.

A greatly expanded national program for biotechnology is envisioned in the "Biotechnology Initiative," a program of federal support for research and development proposed for funding at the \$4.06 billion level for FY1993 (Committee on Life Sciences and Health, 1992). The four areas of the United States containing the greatest concentrations of bioindustry are San Francisco/Oakland (where "Silicon Valley" is being overtaken by "Biotech Bay"), Boston/Cambridge, Greater Los Angeles, and the

Baltimore/Washington D.C. corridor. However, the most significant growth of bioindustry in the United States is yet to come, probably at the beginning of the 21st century. As an indication of the level of interest, recently over 5,000 people participated, either in person or via satellite, in a conference sponsored by the University of California, entitled "Winding Your Way Through DNA." Scientists, and the public at large, are enthusiastic about biological research. In fact, bioengineering is becoming so accessible, a kit to do your own experiments has been marketed in a Christmas catalog for less than \$600 (Douglas and Livingstone, 1987, p. 9).

The growth pattern of biotechnology is moving outside of university research circles. The pattern depends most typically upon the development of a single product, under substantial financial pressure to generate significant promise of results. This then leads to a private capital cash infusion or a corporate buy-out by one of the large multinational pharmaceutical companies. In one recent year, biotechnology stocks were the winners in an otherwise bad time for Wall Street (Edgerton and Misra, 1991). This new approach reflects the increasing interrelatedness of basic and applied research and development. The universities and industry have formed symbiotic relationships never before seen in either the academic or industrial sectors.

On a much lesser scale, but one that is nevertheless significant, biological defense research involving exotic pathogens and toxins is conducted in a number of university and industry laboratories throughout the United States. Given the proliferation of interest in biological warfare by military forces in other countries around the world, the U.S. Biological Defense Research Program is likely to expand in the next few years, encompassing more public and private civilian laboratories.

SAFETY ISSUES

The possible hazardous nature of some biotechnology research and development led the National Institutes of Health (NIH) to establish in 1976 the Recombinant DNA Advisory Committee (RAC), which issued guidelines for rDNA research. The NIH guidelines specify conditions under which risky research can be performed. Research which is perceived as innocuous may be performed under Biosafety Level 1 (BL1) conditions (equivalent to good laboratory practices), while research deemed potentially very hazardous must be done under high security BL4 conditions. Each institution performing biotechnology research and development is required to establish an Institutional Biosafety Committee (IBC), which gives advice on the level at which a particular research project can be performed and monitors research activities. Each IBC annually informs RAC of its activities. Seventeen years of experience with the NIH

guidelines indicate that they appear to protect the workers and the public from potential biohazards while allowing research to proceed relatively unhindered.

The NIH guidelines are mandatory only for those performing government-funded research and for all federal laboratories. In practice, however, university and industry researchers throughout the United States tend to follow the NIH guidelines, due to possible liability should something go wrong.

However, departures have been noted. The IBCs set up to review genetic engineering at public and private institutions have a disappointing record (Gore, 1991). Controversial experiments have been conducted without notice to the relevant committees (Subcommittee on Investigations and Oversight, 1986), and a Government Accounting Office study of these committees found that they were ill-equipped and unwilling to review biotechnology products intended for release into the environment (U.S. General Accounting Office, 1987).

While by far most researchers will follow the NIH guidelines, a small percentage are likely to be unscrupulous or careless. In view of the many thousands of researchers using genetic engineering as a fundamental tool, this small percentage could translate into a significant number of researchers who go their own way, paying little or no attention to the NIH guidelines. In particular, those who do not depend on federal support may ignore the NIH guidelines for reasons that may range from economic (it is less costly to perform research at the BL1 level) to competitive pressure (unrestricted research can be done much faster than that circumscribed by regulations). This group of people, whose activities cannot be easily overseen or monitored, is most likely to suffer accidents, some of which could affect surrounding communities.

Field Testing Concerns

The transition between laboratory research and commercial production of biologically engineered species provides another vulnerable area. Genetically engineered plants and animals seem to be relatively easy to contain, so permission has been given by regulatory agencies, such as the Environmental Protection Agency and the U.S. Department of Agriculture, for more than 400 field tests without apparent negative side effects (Fox, 1992). However, an organism may be deemed innocuous and be undergoing field testing or be used for a purported good, but in the longer term exhibit negative side effects. In addition, genetically engineered microorganisms and aquatic animals and plants will not be easy to contain within a test site, so field testing involving these organisms poses unresolved challenges to regulators.

To prepare for possible untoward effects arising from the field testing of genetically engineered organisms, emergency managers should become involved in the decisions that precede the actual field

testing, because preparations to protect the food supply or citizens may need to be implemented should problems occur.

The history of citizen responses to the appearance of physical symptoms in sites with potentially hazardous chemicals or radiological substances can provide some insights. When symptom clusters appear, they can stimulate rapid and difficult to manage levels of advocacy and concern directed toward public policy makers. When faced with these situations, the policy makers tend to turn to emergency managers. Sometimes, cases have been determined to be a valid exposure to toxics; other times, this has been unproved. Nonetheless, the demand upon emergency managers to be knowledgeable and responsive within limits of existing technology is the same, whether it involves biological, chemical, or nuclear material.

Manufacturing

The NIH guidelines restrict the amount of genetically engineered organisms that can be grown at one time in a fermenter to 10 liters. Anyone wishing to ferment larger quantities must request permission to do so from RAC. In practice, most manufacturing processes use innocuous organisms that are unable to grow outside the laboratory. For example, *Escherichia coli* (*E. coli*) is a normal inhabitant of the animal gastrointestinal tract, but certain strains can cause infections. However, the genetically engineered *E. coli* used to manufacture human insulin has been weakened to the extent that it cannot survive in nature. So a manufacturer preparing to set up a production facility to produce human insulin need only inform the local IBC of this fact, and the IBC will probably only monitor the process at infrequent intervals.

The most common exception to this procedure involves the manufacture of vaccines against virulent organisms. In these cases, which are in fact not so common, some operations will take place under BL3 or BL4 conditions, which will be carefully monitored by the local IBC and other authorities. Research done at BL4 facilities is particularly easy to monitor, since there are only five of them in the United States¹. Although problems with routine manufacturing processes are unlikely, continued vigilance is essential.

¹The five BL4 facilities are located at the Centers for Disease Control's Center for Infectious Diseases in Atlanta, Georgia; the U.S. Army Medical Research Institute for Infectious Diseases at Fort Detrick, Maryland; at the National Cancer Research Facility at Fort Detrick, Maryland; at the National Institutes of Health at Bethesda, Maryland; and at Plum Island Animal Disease Center, New York.

Transportation

We do not know how many packages of etiologic agents are shipped annually in this country. (According to the Department of Transportation, an etiologic agent is a "viable microorganism, or its toxin, which causes or may cause severe disabling or fatal human disease.") Shippers are supposed to adhere to shipping regulations, which include container size, strength, packing materials required, etc. Incidents involving damaged packages are increasing. Five years ago, the Centers for Disease Control testified that they received an average of three calls per year of verified damaged packages containing etiologic agents (Hermann, 1991, p. 37). However, the calls now average two per *week*, with about six per year resulting in a possible exposure.

Accidental Releases

The professional safety guidelines (BL1 through BL4) presume the integrity of the laboratory itself. They do not cover situations where containment has been breached, such as the accidental release of biological threat agents resulting from containment failure, either at the research laboratory, the manufacturing plant, or in transport. Thus, the NIH guidelines do not cover what to do if a facility for biotechnology research or manufacturing is damaged or destroyed by a hurricane, tornado, earthquake, or other natural disaster. As far as the authors are aware, there are no other regulations or guidelines at the federal level that cover such eventualities. Experience has shown that this is a potentially serious shortfall: after California's Loma Prieta earthquake in 1989, 46% of the 490 documented releases of hazardous materials occurred in a laboratory environment (Selvaduray, 1991).

Criminal Activity

In a field as commercially lucrative as biotechnology, financial incentives are high. A RAND report on insider crimes in nuclear facilities revealed that by far the most frequent motivation for the crimes was personal gain (Hoffman, 1990). A similar situation could occur in a field as profitable as biotechnology.

Biological hazards may be deliberately engendered by a variety of misanthropes or criminals, for example, disgruntled employees bent on revenge, blackmailers, or terrorists who have a political agenda. Biological agents and toxins seem potentially well suited as weapons for persons who act alone or in small groups, because they are deadly in small doses, are easily concealed and transported, and can be activated by relatively untrained persons. Biological agents have the potential for being weapons of mass destruction, and some pathogens that could be used as crude biological weapons are readily obtainable. For instance, the common food and waterborne pathogens *Salmonella*, *Shigella*, and *Staphylococcus* could

be procured from a local clinical laboratory. Low levels of technology are required to grow a batch of any of these agents and make a paste out of the cell mass: it could be done by a technician in any clinical microbiology laboratory or biotechnology firm. Transporting and inserting the paste into a water supply would be easy. The ease with which a public water supply could be sabotaged was demonstrated when the radioactive material U235 was dispersed in the New York City water supply in 1981, potentially affecting millions of citizens. The water was intentionally contaminated with U235. While traces of U235 were found in water samples drawn from many areas of New York City, the levels were deemed to be nontoxic. Intensive investigation by local, state, and federal law enforcement proceeded over a period of months, and the individual who caused the contamination was never identified.

Intentional release of such pathogens, particularly airborne viruses, could affect an extremely large area. As little as a few kilos of anthrax spores released in aerosol form could infect millions in our urban areas. To illustrate, the U.S. Army conducted tests of biological agents in the 1950s, using simulants—bacteria or viruses considered to be benign—and releasing them in urban areas, including Minneapolis, St. Louis, New York City, and San Francisco. These experiments showed the ease with which biologicals can be released, and that even relatively clumsy tactics did not arouse either public or law enforcement attention. One of the conclusions was that "a large proportion of the working population in downtown New York City would be exposed to disease if one or more pathogenic agents were disseminated covertly in several subway lines at a period of peak traffic" (U.S. Department of the Army, 1968, p. 23).

Biological agents are also inexpensive. In terms of costs per kilometer for producing mass casualties, conventional weapons cost about \$2,000, nuclear \$800, chemical weapons \$600 and biological weapons \$1 (McGeorge, 1990, p. 15).

Use or planned use of biological agents by criminals is not unknown. Botulism is most commonly known as a food poison, and was first discovered in 1793. It is toxic in very small doses; 0.1–1 microgram can be fatal. There are at least two instances where botulism was planned for use by criminals. In 1980, a Red Army faction group "safe house" in Paris was raided, and the resident, a microbiologist, was found to be culturing botulism spores in the bathtub. In 1984, two Canadians with criminal backgrounds were caught by accident, ordering botulism spores by phone, after they had already received tetanus spores from an earlier order (Douglas and Livingstone, 1987). Ricin, which is made from castor beans, may be one of the oldest known plant poisons. Although less toxic than botulinum, it is also poisonous in small doses, and easier to use. In 1978, the Bulgarian secret service used ricin to assassinate one dissident and harm another (Elmsley and Pallister, 1978). In 1984, the FBI obtained

one ounce of ricin in a film canister from an individual who had manufactured it himself (Elmsley and Pallister, 1978).

Product tampering is increasing throughout the world; Japan especially has been affected by this type of crime. So far, chemicals have been used—the cyanide poisoning of Tylenol in 1984 and 1986, as well as the sabotage in England of baby food during the spring of 1989, have received mass publicity. It is therefore likely that most terrorists, potential extortionists, and others are aware of this type of crime and how it can be deployed to achieve their purposes. Biological agents can be used as easily as chemicals, but can produce much greater casualties. Dating back to 1955, a special committee of the National Research Council assessed the food industry as being vulnerable to chemical, biological, and radiological agents (Civil Defense Foods Advisory Committee, 1955). Small incidents can result in large damages; the discovery that three Chilean grapes were poisoned with cyanide resulted in several hundred million dollars of damage and bankrupted more than a hundred growers and shippers. Recently, in California, taco shells were found poisoned by the extremely toxic pesticide endrin ("Endrin poisoning . . .," 1989). As recently as March 1992, police in Fairfax, Virginia, charged a man who opened a vial and exposed 20 people to what he falsely claimed was the bacteria anthrax ("Man charged . . .," 1992). Communities need to be able to quickly assess and respond to these threats.

The 1990s may see corporate extortions take on an exotic aspect, to include the threatened or actual use of biological agents to contaminate consumer products or corporation facilities. Such actions could be committed by foreign or domestic terrorist groups, religious or political zealots, and other individuals with a psychological predisposition for revenge or mass murder to achieve an individual or group goal (Van Zandt, 1993).

A recent report prepared for the U.S. Armed Forces Medical Intelligence Center, discusses arguments for and against the likelihood of terrorist use of biological weapons. The technological barriers to use were not found to be insurmountable; rather, the main deterrent so far seems to have been possible adverse reaction of the terrorists' own support base. However, the report concluded that some of the negative aspects of the use of biological weapons (from the terrorists' perspective) might be becoming less important. The trend of mass killings through terrorist acts has been recently observed in multiple airline bombings, and one might foresee a reduced reluctance on the part of terrorists to take the lives of thousands of innocent citizens. The Congressional Office of Technology Assessment (OTA) rates the odds at even or slightly higher that a chemical or biological terrorist attack will occur (U.S. Office of Technology Assessment, 1991).

The proliferation of biological weapons has direct relevance to future terrorist activities because terrorists are unlikely to have access to these weapons unless they are supplied by a nation developing them. Some security analysts claim that 10-15 nations possess a capacity that could be used to develop offensive biological warfare (Douglas and Livingstone, 1987). Several of these states have been associated with the support of terrorist groups. The OTA report references the high probability of increased technology transfer involving toxic biological and chemical agents, citing the recent transfer of chemical weapon technologies from Germany to Libya. This event shows that such transfers are possible even within a very structured state with existing laws barring such transfer. Stopping transfers of this nature will be even more difficult in less stable states. Notably, Iranian President H. Rafsanjani has stated publicly, "We should fully equip ourselves both in the offensive and defensive use of chemical, bacteriological, and radiological weapons. From now on, you should make use of the opportunity and perform this task" (Foreign Broadcast Information Service, 1988).

An official Iraqi memorandum indicates that Baghdad has been developing biological weapons since 1986 ("Document says . . . ," 1992). Advance preparation is important, as perceived risk of retaliation may be a factor in the choice of using chemical or biological weapons, as evidenced by the Iraqi use of such agents against the Kurds and the subsequent reluctance to use them against the U.S. military. No one knows at this time if the current Iraqi government will attempt to test the Clinton Administration's resolve by arming terrorists with biological or other weapons of mass destruction against either U.S. or friendly foreign interests, or in renewed attacks against the Kurdish people.

An incident in the former Soviet Union indicates that country's interest in biological weapons research, demonstrates a probable containment breach, and shows the government's reluctance to acknowledge a problem. In 1979, an unusual outbreak of anthrax led to 64 deaths. The official Soviet explanation was that the deaths were caused by ingestion of contaminated meat. But interviews with the physicians who treated the patients noted that they all died from pneumonia and meningitis. This presentation is consistent with exposure from inhalation. The pathologist on the case tried to publish the findings but was blocked by the KGB. The KGB also removed the diagnosis of pneumonia from the death certificates. Most of the victims worked in a ceramics factory a few hundred yards downwind from Military Compound 19. The Soviets later acknowledged the compound enclosed a secret military microbiological research institute. Some now believe that the functions previously performed at Compound 19 have been transferred to a facility on Lake Baikal in Russia (Gumbel, 1991).

EMERGENCY PREPAREDNESS: CURRENT STATUS

As a society, we have learned that each new technology, such as chemicals or nuclear energy, has brought with it a varying range of serious health side effects. While such side effects can be mitigated by adherence to proper human behavioral and material protocols, individuals do make mistakes, containment material product failures do occur, and psychopathic or criminal acts are possible.

Wise public officials and emergency managers should now include biological incidents among the various risks for which they plan. Planning will be required for naturally occurring epidemics, biological terrorism or war, and for unsafe practices in the biotechnology industry. As is the case in all response planning, a systematic and rational approach to identifying and addressing potential problems will be required.

This work has begun. At the national level, the Federal Emergency Management Agency (FEMA) is responsible for coordinating national response to any disaster, regardless of its initiating event. The recently developed Federal Response Plan assigns tasks for 12 emergency support functions and provides for an "advance element," to be readily fielded, should a disaster be anticipated. This response capability is still under development, and needs continued attention and support to reach its full capability. The current focus on natural disasters will need to be revisited to incorporate additional organizations which should be involved in a biological emergency response.

Congressional concern over biological warfare has been significant as well, with Rep. Glen Browder recently chairing an inquiry for the House Armed Services Committee on this country's preparedness for nuclear/biological/chemical warfare (NBC). The General Accounting Office reported last year that U.S. forces were not being adequately trained or equipped to fight on chemical or biological battlefields, and funding for these programs declined 25% between 1986 and 1991. However, the FY1993 defense budget includes \$604 million for NBC-related activities, including \$250 million to develop and purchase chemical and biological agent detectors and protective gear. The Congressional attention thus far has concentrated primarily on military preparation in a battlefield environment. Civilian preparation or protection for our communities has not yet been a focus for development (Reed, 1992).

Efforts to coordinate responsibility and communication in the federal response to terrorism, including the intentional use of biological agents, began in the 1970s (U.S. Office of Technology Assessment, 1991). From an investigative standpoint, the Federal Bureau of Investigation (FBI) has been designated as the lead agency in biological crimes in this country, following a model developed by the Department of Energy for nuclear emergencies. The FBI has the responsibility to investigate criminal acts that may include the intentional use of nuclear, chemical, biological, or toxic agents. Sabotage,

intentional dispersal, product contamination, and the threat to accomplish any of these acts are all covered under various federal laws under the FBI's jurisdiction.

As in any extortion or threat investigation, the FBI can call upon the expertise of the National Center for the Analysis of Violent Crimes, which will provide a criminal investigative analysis (psychological profile) of the extortionist or threatening individual. The assessment, combined with other sources, is then used by FBI headquarters and the local FBI field office to determine the federal level of response, and the number and type of resources to be mobilized to meet the identified threat. The investigative response would be led by the FBI, with the non-criminal, emergency management aspect of the incident coordinated by FEMA in support of state and local emergency management officials.

Concerned federal, state, and local agencies have begun practicing this response capability and using their credibility threat assessment techniques in real-world incidents. This assessment and response capability can be activated by contact with any FBI field office, and response activities would proceed through the same channels as for natural disasters.

In addition, the federal response to terrorism, including the intentional use of biological agents, involves the Policy Coordinating Committee on Terrorism (PCC/T), first known as the Interagency Group on Terrorism at its inception in 1982. The PCC/T is chaired by the Department of State's Coordinator for Counterterrorism, and has 25 federal organizations as members. Within the PCC/T is a very important subcommittee, the Technical Support Working Group (TSWG), which administers the National Counterterrorism Research and Development Program. Funding for TSWG efforts was first authorized by PL 99-349 in 1986 with initial funding of \$10 million for the development of detection and emergency response technology. The primary technology projects relevant to biological agents are (1) a rapid response, transportable, semitrailer-sized laboratory for detection and identification of biological and chemical agents, and (2) an inexpensive protective hood for ten to thirty minutes of emergency ocular and respiratory protection against biological or chemical agents. Unfortunately, further progress bringing these developing technologies and others to a field operational status has been inhibited by a progressive reduction in federal funding from the \$10 million in 1986 to approximately \$2 million currently².

Some individual states, such as California, have convened working groups through their emergency services offices, consisting of elements of the different state agencies which would be active

²Project development by Computer Optecnomics of Annapolis, Maryland, with project management by the U.S. Environmental Protection Agency and technical assistance by the U.S. Army Chemical Research, Development, and Engineering Center.

in a biological response. At the state level, hazardous materials contingency plans and nuclear emergency response plans can provide the basis for planning for a biological disaster.

Plans are underway to convene a conference of emergency managers and microbiology researchers, with the goal of establishing common terminology and mutual understanding of risks. Federal funding has been requested, and the conference is anticipated to convene in late 1993. Results of this conference will guide future efforts.

PRUDENT PRECAUTIONS

Disease will be a continuing element of our global environment. Biologically-engineered plants, animals, and microorganisms will provide benefits to humanity beyond our imaginations. But criminal and military applications of this technology will continue to threaten our society. Emergency managers, in the multihazard context, need to include considerations for biological hazards in preparedness efforts, mitigation measures, response procedures, and recovery plans. Specific actions should include the following:

- 1) *Forge a partnership between business and government.* Industry/emergency management cooperation is essential at the national, state, and local levels. The agreement must include sharing information, risk evaluation, joint training opportunities, a review of resources, and frank discussions about notifications and responses. In view of all the uncertainties, there is a need for close cooperation. The process of addressing chemical hazards in our communities has provided both horror and success stories. Both offer learning opportunities as we broaden our perspectives to include biological threats.

A national working group should examine all aspects of biotechnology, from its funding and priorities to its safety. This group must include representation from emergency management. States can provide the focal point for information and expertise for their local jurisdictions. Local governments will be in the front line of coordination with companies, research facilities, and others in their area, to make sure threats are appropriately assessed and resources identified.

- 2) *Build upon our base.* Apply the existing multihazard approach to emerging threats from biological hazards. Start with the knowledge base of experience, but remember that the highly technical challenge posed by biohazards will require a much closer degree of coordination and resource sharing among disparate federal and state agencies, and an expansion of the network to include both investigative and law enforcement elements.

Prototype plans and protocols should be developed to assist states and communities in addressing this hazard. Pilot projects which can have national replicability should be considered.

- 3) *Support for research and development of hardware and knowledge systems is needed.* New, effective monitoring equipment; protective devices, such as masks, and portable shelters; filters for rooms and vehicles; or other items may be required. Stockpiles and transportation

procedures need to be developed. Epidemiology networks need strengthening, on a national and worldwide basis. Response plans should be developed which include stand-by orders for governors or the President based on biological hazards. Research and treatment protocols may need to be revisited. Perhaps new laws or regulations are appropriate. At present, monitoring equipment and protective devices exist in a limited number of locations, primarily under military direction. The modification of such equipment for use by civilian emergency response teams is essential.

Emergency managers need access to a knowledge base and resource system which is focused to their needs and which can provide on-call consultation in a manner parallel to resources for chemical and radiological hazards.

- 4) *Devote special attention to criminal and terrorist potential.* The U.S. Office of Technology Assessment Task Force on Technology and Terrorism has conducted a comprehensive review, with recommendations for action regarding the intentional use of biological and chemical agents against the public. These recommendations should be implemented, with special attention paid to the activities and potential of the Technical Support Working Group. Priority should be given to those activities which have the greatest potential for field operational status for emergency management use.
- 5) *Training and exercises must be priorities.* Training programs need to be developed for everyone, from maintenance workers, such as those described in the first incident in this paper, to the on-site response team, to local, state, and federal employees and elected officials. Regularly scheduled exercises and drills, including the testing of both management skills and field devices and techniques, are essential. Depth of knowledge throughout the emergency response structure will be needed to assure that appropriate decisions are made.

At the federal level, the programs resulting from the Superfund Authorization and Recovery Act and the Hazardous Materials Transportation Uniform Safety Act can serve as models for efficient mechanisms for fielding large training initiatives. At the state level, California's Hazardous Materials Training and Education Program, which has provided cost-effective training to over 8,000 people in less than four years, can be a model for biological hazards training.

CONCLUSION

Historically, each promising new technology has always brought risks. Public policy makers and the constituents to whom they report characteristically turn to emergency management professionals when such issues materialize in their community.

Emergency management is no longer just a matter of responding to disasters when they occur. The profession now demands the identification of potential problems, development of response plans, mitigation of hazards where possible, and preparation not only for government agencies but individual citizens. This paper has described a hazard area where this process is just beginning, and offers an approach to this emerging challenge.

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