

ADVANCED TECHNOLOGY TO COUNTER
BIOLOGICAL TERRORISM

A PRESENTATION TO THE
INTERNATIONAL CONFERENCE ON
THREATS IN THE TECHNOLOGICAL AGE
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“The U. S. shall give the highest priority to developing effective capabilities to deter, prevent, defeat, and manage the consequences of nuclear, biological, or chemical (NBC) materials or weapons used by terrorists.”

President William J. Clinton, *Presidential Decision Directive 39*¹

“I declare a national emergency with respect to the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by the proliferation of nuclear, biological, and chemical weapons (‘weapons of mass destruction’) and the means of delivering such weapons.”

President William J. Clinton, *Executive Order 12938*, November 14, 1994²

Study Background

Last year the Potomac Institute for Policy Studies performed a study of Countering Biological Terrorism, which concluded in a conference held in August 1997. It was considered that Weapons of Mass Destruction (WMD) were a grave threat to the US, and that the most likely way they would be used against us was through terrorism. Of the various WMD, biological agents seemed to be the most likely to be accessible to terrorists, and potentially one of the most devastating. Additionally, there was concern that the US was not as prepared as it should be to combat the threat.

The Institute received backing from the Smith Richardson Foundation. We put together an accomplished group of consultants that was able to address in detail the technical issues raised in the range of disciplines that impact countering biological terrorism, including public policy, microbiology, strategy, psychology, terrorism, and others. Finally, we presented the results of our research in a conference in August, the proceedings of which are available from the Institute for a nominal fee to cover costs. Study participants included the following:

Dr. Yonah Alexander, George Washington University:
Super Terrorism

Dr. Jerrold Post, George Washington University:
Psychodynamics of Terrorist Groups

GEN Al Gray, Former Commandant, USMC:

¹ Clinton, William. *Presidential Decision Directive 39*. Unclassified quotation in Clark, William, “U. S. Consequence Management Response to C/B Terrorism,” Office of Emergency Preparedness, U. S. Public Health Service, Rockville, MD. Undated. Slide #30.

² President William J. Clinton, *Executive Order 12938*, November 14, 1994. Renewed again on November 12, 1997.

Military Support to Civilian Authorities for CBT
Dr. Robert Kupperman, Senior Fellow, CSIS:
Threat Environment and Advanced Agents
Dr. Bert Brown, Former Public Health Service, and Al Meltzer:
US Capabilities for BT Medical Consequence Management
Dr. Richard Crowell, Past President, American Microbiology Society:
Likely Threat Pathogens
Dr. Regina Dugan, Defense Advanced Research Projects Agency:
Technology to Counter Terrorism
Peter Lejeune, Former Director, New York City Emergency Planning:
Federal Plans to Counter Biological Terrorism
Mick Donahue, Former Director, CIA Technical Operations Support:
Terrorist Group Dynamics
Peter Hinkle, Former Army Special Forces Counter Terror Operations:
Intelligence for SOF Responses to Counter Bioterrorism
Ms. Stephanie Tennyson, Institute Staff Member,
CBT Arms Control
Dr. Randy Curry, University of Missouri:
Advanced Electro Technologies to Counter Biological Agents
John Bosma, PIPS Research Associate:
Possible Infection Paths for Biological Terrorism
David Siegrist, PIPS Research Fellow and Study Director:
Strategy and Summary Papers

Since our study, there have been a number of publications on the strategic importance of countering WMD terrorism. The US *Defense Science Board report on DoD Responses to Transnational Threats* is an outstanding document that deserves wide attention, calling for DoD to make a top-to-bottom effort to combat WMD, not only for force protection abroad, but because homeland defense is a core DoD mission.³ Elsewhere, a majority report of the Senate Government Affairs Subcommittee on International Security, Proliferation, and Federal Services, *The Proliferation Primer*, takes the Administration to task for not doing enough to control the spread of WMD, and cites proliferators. Professor Richard Betts is in the new edition of *Foreign Affairs* with an article on the way WMD changes International Relations. John Steinbruner is in the current *Foreign Policy* with another, “Biological Weapons”, which also contains an important citation for *Controlling Dangerous Pathogens*, a National Academy study available in their website reading room, which discusses the first U.S. cooperative projects with former Soviet *Biopreparat* laboratories. The recent *New Yorker* article (March 9, 1998) by Richard Preston on “Biological Armageddon” features Dr. Ken Alibekov, former deputy director of *Biopreparat*’s offensive biological warfare program, who participated in the Potomac Institute’s conference last year, where he first came forward publicly with

³ The Defense Science Board 1997 Summer Study Task Force on DoD Responses to Transnational Threats: Volume I, Final Report.” Office of the Undersecretary of Defense for Acquisition and Technology, Washington, D.C., October 1997.

his chilling accounts of advanced Soviet biological threats that may be being continued by the Russian military, or indeed have become available to others through the emigration of Russian arms experts.

Threat

In February, two men were arrested in Las Vegas, Nevada on suspicion of possessing anthrax. Later it was shown that it was animal anthrax vaccine, and one of the two suspects was released. The other, Larry Wayne Harris of Ohio, was detained for probation violation. He had been convicted of fraud in 1995 in connection with obtaining bubonic plague cultures from a lab in Maryland. Procedures to obtain virulent cultures had been tightened since his arrest.

FBI Director Louis Freeh testified before Congress on 28 January 1998 on threats to US national security. He noted that the FBI, which has jurisdiction over terrorism in the US, had opened over 100 cases in 1997 about the threat, development, or use of WMD, including biological agents. This is more double the amount from the year before. Freeh noted that a significant fraction of the cases involved threats that had no basis in fact, and that most of the actual interest in biological threats seemed aimed against limited personal targets. However, up to approximately 30 investigations concerning WMD may be ongoing at the FBI.

The FBI is concerned about terrorist groups in its recent report on terrorism⁴.

Supporters of formalized terrorist groups -- such as the Egyptian Al-Gama'at Al-Islamiyya, HAMAS, and Hizballah -- continued to view the United States as an attractive refuge and staging area. Some supporters in the United States are believed to be conducting criminal activity -- to include military-style training -- in support of terrorist groups' objectives. With the conviction of Shaykh Omar Abdel Rahman -- the spiritual leader of the militant Egyptian Islamic Group-- and the detention of HAMAS leader Musa Abu Marzook, it is possible that members of formal terrorist groups may be considering some form of retaliation.

Finally, loosely-affiliated extremists continued to view the United States as both a staging area and a target. Some of these unilateral radicals -- who adhere to the worst excesses of hatred spawned by a variety of international conflicts -- have demonstrated the ability to use advanced technology in the United States, travel undetected here, and circumvent the letter and spirit of U.S. laws. These militants represent the most difficult international terrorist challenge to the law enforcement and intelligence communities.

⁴ Federal Bureau of Investigation. *Terrorism in the United States*.

Terrorists in the United States continued a general trend in which fewer attacks are occurring in the United States, but individual attacks are becoming more deadly.... It is likely that the United States will continue to face the threat of "spectacular terrorism" for the foreseeable future.

Extremists in the United States continued a chilling trend by demonstrating interest in -- and experimentation with -- unconventional weapons. Over the past ten years, a pattern of interest in biological agents by criminals and extremists has developed:

-- In 1984, two members of the Rajneesh religious sect in Oregon produced and dispensed salmonella in restaurants in order to affect the outcome of a local election. Seven hundred and fifteen persons were affected. There were no fatalities.

-- In April 1991, several members of a domestic extremist group called the Patriot's Council in Minnesota manufactured the biological agent ricin from castor beans and discussed using it against federal law enforcement officers. The amount of ricin produced could have killed over 100 people if effectively delivered.

-- In May 1995, a U.S. person illegally obtained three vials of bubonic plague from a firm in Maryland. He was arrested and charged with fraud. It is still unclear why he ordered the vials.

These events indicate that terrorists and other criminals may consider using unconventional weapons in an attack here sometime in the future.

The Defense Science Board has recounted an example of a rogue state launching a covert terror campaign against the U.S. President Reagan bombed Libya in April 1996 in retaliation for the bombing of the LaBelle disco by Libya. Popular belief was that that virtually quelled Libyan terrorist activity. However, the Defense Science Board has recently revealed that the Libyans continued to wage a covert terrorist campaign for years through transnational actors.⁵ Three days after the Libyan terrorist training camps and a personal residence of Moamar Qadaffi were attacked, the Libyans purchased an American hostage in Lebanon and executed him. In September 1987, Abu Nidal, working for Libya, hijacked Pan Am 73 causing the death of several Americans. In April 1988, the Japanese Red Army, under contract to Nidal, bombed the USO in Naples, killing an American serviceman. Later a Libyan agent was arrested in New Jersey with pipe bombs intended

⁵DSB, p.15-16.

for New York City. In December 1988, Pan Am 103 was bombed at Libyan direction. (Other virtually undetectable bombs were confiscated by the German police, killing one). The terrorist group attacked Libyan dissidents in America, and even recruited a Chicago street gang to fire “Stinger”-type missiles at U.S. airliners, a move that was interdicted. This series of episodes illustrates the ability and willingness of transnational adversaries to mount a sustained covert campaign against that the U.S. was only partially successful in countering, while escaping massive retaliation. The ability of rogue states to access potential US domestic perpetrators is also a particular concern.

In another example, the Defense Science Board goes on to describe the World Trade Center bombers, headed by Ramzi Yousef.⁶ They started in May 1990 by assassinating Rabbi Meir Kahane, an Israeli activist, in a homicide that initially seemed to not have foreign policy implications. The group went on to bomb the World Trade Center, using conventional explosives (although the judge was convinced they had added cyanide to their bomb). However, they had a goal of mass destruction. The intent was to collapse one office tower into the other, bringing them both down, with the possible loss of life of 250,000 people. (They were unsuccessful in part because the parking spot by the structural member they had targeted was unavailable when the bombers arrived). Ramzi Yousef explained to an FBI agent on his transport back to America that the U.S. had killed 250,000 people at Hiroshima and Nagasaki, and that if a similar number of Americans died, the US would realize it was in a real war. The group’s July 4, 1993 “follow-on plan” was to inflict 100,000 more casualties by destroying bridges, tunnels and other infrastructure and symbolic targets. The plan was interdicted, according to some press reports, when the FBI renewed its contacts (and payments) with an informer in the group. Ramzi Yousef himself evaded capture for two years, in the meantime planning to down thirteen international flights on one day (one Philippine flight was attacked in a field test) as well as planning to assassinate the Pope.

Laurie Mylroie has pointed out in *The National Interest* that Yousef was traveling on a passport originally issued to a Kuwaiti citizen who was arrested by Iraqi security services during the occupation and presumably executed⁷. This suggests that Iraq may have been the sponsor of Yousef’s activities, including the New York attacks. If Iraq gets the opportunity to supply an individual such as Yousef with dry biological agent from a renewed weapons program, is it prudent to assume that it would not do so? An additional disturbing development is the newspaper report that Iraqi bioweapon scientists have moved to Libya to continue their work and transfer technology.⁸ As seen, Libya has in the past, and may be continuing, to wage a covert terror campaign against the U.S..

⁶ Ibid, p.16-18.

⁷ Laurie Mylroie, “The World Trade Center Bombing”, *The National Interest*, Winter 1995.

⁸ Joshua Sinai, “Gadhafi and Saddam in Cahoots,” *Washington Post*, January 29,1998, p. 19.

Selected Study Findings

The US Cold War Defense paradigm needs to be reconsidered systematically in the light of the emerging threat. In the past, deterrence was central to preventing attack, arms control was a leading approach to security, and intelligence featured collection of overhead imagery. All those approaches need to be questioned in the light of a different threat. Biological terrorism is difficult to deter because of its accessibility, lethality density, and covertness of deployment. Arms Control is limited as an approach, because the technology to create deadly biological agents is widely available and dual-use. Overhead imagery systems, moreover, have limited utility collecting against many targets of interest. A Post Cold War an integrated approach to a coordinated (foreign /domestic, federal/local, civil/military) national security strategy needs to be further developed.

It was a conclusion of the Phase One study that asymmetrical US superiority in biotechnology must be harnessed to overcome US vulnerabilities to asymmetrical biological threats. Biological agents are relatively fragile, and take some time to achieve their effects. Technical means are needed to detect biological releases, identify the sources, and prevent or minimize damage to human hosts should that release occur. Having effective detectors deployed would enable a strategy of resource sharing that would minimize the need for duplicative equipment sets around the country. Due to the incubation period of diseases, medicine could be administered before symptoms start to present, improving greatly the chances for recovery. The initial Potomac Institute study identified advanced medical countermeasures in the development stage that were highly encouraging, in that they were effective against disease from several different sources by attacking homologous (common) factors in the microbes. Advanced technology represents a promising approach for long term mitigation of the threat from biological agents.

The US needs to develop a comprehensive strategy that features a time phased approach, so that an initial plan can be developed and the highest priority immediate acquisition needs are identified. However, the technical base appears to hold the key to regaining the initiative from potential terrorists, and eventually overcoming their threat. Focused research needs to be further developed and made available through a dual use approach that leverages the private sector to make the technology affordable and available.

Near term, a detailed plan and coherent organizational structure are needed to forge a strategic national effort to counter biological terror. The FBI is currently developing an interagency "concept plan" as the lead agency in crisis management. The Directorate of Military Support (DOMS) is also developing a plan for military Support to Civilian Authorities to alleviate the effects WMD terrorism. Both these are useful, but fall short of the comprehensive plan needed. Currently, a Presidential Commission headed by Dr. John Deutch is going further in recommending changes in the organization of the Federal response to countering WMD terror. The National Security Council is currently

staffing a plan to change US Government organization to counter terror and create a “Czar” to coordinate an overall response. This appears to be sorely needed.

Medium term, the Institute has recommended a strategy to counter biological threats that capitalizes on their latency. Given functional, proliferated biological sensors, centralized limited assets could be shipped in and brought to bear prior to the worst effects of biological terrorism manifesting themselves. For instance, inhalation anthrax generally takes at least a day (sometimes six) to incubate in a human host. If appropriate antibiotics are administered before the onset of symptoms, there is an relatively favorable prognosis for recovery. (Conversely, if treatment begins after symptom onset, mortality significantly increases regardless of treatment).⁹

Longer term, the US needs to develop advanced medical and other countermeasures that will overcome a broad spectrum of threat biological agents, and regain the initiative for the defender (instead of the terrorist), making a biological attack much less likely, while significantly mitigating its effects if it does nevertheless occur.

The question arises of what is an appropriate national budget. Kaufman, Meltzer and Schmid of the Centers for Disease Control and Prevention have done a useful analysis of the economic costs of a deliberate release of anthrax, as well as two lesser threats.¹⁰ They determined that the economic cost of an exposure to anthrax is approximately \$26 billion per 100,000 people exposed. This counts the cost of prophylaxis, as well as the lost wages of the decedents in an attack. The authors note that insurance company actuaries determine that a fair price to pay for insurance is 5% of the estimated losses that are estimated to occur. There are approximately 200 million Americans who live in urban environments, ones more likely to be targeted by terrorists. For illustrative purposes, we may determine a figure that might be reasonable for “insurance” (actually a budget to prevent and mitigate the disaster) against a biological attack. This comes to a large number. Nevertheless, it might be appropriate to have a \$10 billion line item in the US national budget to combat biological terrorism. Obviously, the exact amount is open to question, but the Institute considered that this approach was a useful starting point for a discussion.

⁹ “Improving Civilian Medical Response to Chemical or Biological Terrorist Incidents: Interim Report on Current Capabilities” by the National Academy of Sciences Committee on R&D Needs for Improving Civilian Medical Response to Chemical and Biological Terrorism Incidents. Paper is available at the Reading Room of the National Academy Press, <http://www.nap.edu/readingroom/reader.cgi?auth=free&label=ul.book.NI000850>

¹⁰ Arnold F. Kaufmann, Martin I. Meltzer, and George P. Schmid. “The Economic Impact of a Bioterrorist Attack: Are Prevention and Postattack Intervention Programs Justifiable?,” in *Emerging Infectious Diseases*, Vol 3 Number 2, April/June 1997.

TECHNICAL ISSUES

The initial study identified certain advanced medical and nonmedical countermeasures programs that have significant potential to counter biological terrorism. Given a practical, proliferable detection system and a broad spectrum medical countermeasure, civilian defense could take advantage of the attack latency, the incubation period of the disease, to minister to all those exposed to the agent with minimal losses, thus making any attack less attractive and so less likely in the first place. Of course, detectors and medications would also be of tremendous benefit against naturally occurring pathogens.

A key here is the dual use nature of many of the technologies needed to counter the biological threat. Microbe detectors are needed to assure high meat quality, for instance, in addition to monitoring intentional releases. “Sick Building Syndrome” creates a market for air filters in building HVAC systems that can remove particles of the size optimal for infecting occupants with intentional biological releases. New emphasis on monitoring particulates by the Environmental Protection Agency may also create the opportunity to monitor spores and other possible manifestations of an airborne biological attack. A plan must be developed for dual use infrastructure procurement and implementation to maximize cost effectiveness against the spectrum of threats.

Technology development often responds to both the “push” of emerging technologies, and the “pull” of unmet operational requirements. In this way, opportunities are recognized by being aware of new applications for emerging technologies, as well as driving development of technological solutions to user needs. Although resources are now limited to develop and acquire technology for this purpose, it is nevertheless important that the most promising technologies be recognized and nurtured as soon as possible. If the perception of a threat of biological terrorism suddenly increases, say accompanying an incident or threat of intentional release, the planning should have been accomplished previously to be able to go forward rapidly with an implementable investment strategy.

Non-Medical Countermeasures

In its initial study, the Institute considered what we called the matrix of the threat. Different kinds of terrorists would have different kinds of agents, and potentially different targets, all of which would have different dependencies, any one of which could break the succession of capabilities the terrorists would have to achieve before they could implement an effective attack. Since funds are limited to counter biological terrorism, the Institute recommends identifying the most likely scenarios and agents, and develop means to counter them at critical junctures, rather than attempting to neutralize all aspects of the threat.

In our estimation, one of the targets most likely for biological attack are subway systems. Dr. Randy Curry and Dr. Thomas Clevenger at the University of Missouri-Columbia have conceptualized an innovative approach to decontamination that the

Institute would like to see assessed for its applicability to defending subway systems, even without reliable, near-real-time biological agent detectors.¹¹ Sections of subway tunnels could be fitted with particle detectors. When a rush of particles of appropriate size was detected, an electrostatically charged mist of hydrogen peroxide would be generated. Because of its charge, it would rapidly cling to particles of agent (if it were present). By attaching, the particles would grow in size and precipitate out of the air flow more rapidly, making them less of a threat. Once sprayed, an ultraviolet source (such as a mercury lamp) could be activated in the subway tunnels. (Studies at Old Dominion University show that pulsed UV is more efficient than continuous in destroying biological agents, suggesting a rate dependent phenomenon). The hydrogen peroxide increases coupling of the UV energy into the attached particles, enhancing system efficiency. (Experiments demonstrating this enhanced energy coupling have been conducted at the University of Missouri, Columbia, and elsewhere). Reflective surfaces could also be installed to take advantage of subway topology, and further increase efficiencies. The UV source also creates free OH radicals from the hydrogen peroxide, making the pulse power more efficient in destroying the attached biological agent. The light would obviously be turned off when trains were in view to protect the passengers from exposure. UV is also effective at breaking the molecular bonds of chemical agents, mitigating their effects in the event of a nerve gas attack. Tax payers might well pay for an effective safety device to counter biological terrorism, especially if health studies could show increased protection from, say, influenza or other germs, which are already present in the subways.

One of the technologies needed is computer “understanding” of particle counts from detectors, such that the sensors may deliver both low false alarms of deadly agents in, say, pollen streams, but assured alarms of such agents if they are indeed present. These low false positives and low false negatives are essential for a practical automated detection system, and advanced computing systems that are well within the state of the art can help achieve them, if attention is drawn to the need.

As to biological sensors, important work is being done, but current production models may often require 45 minutes to detect one of several agents they are programmed to identify. Most of the challenges come not from increasing sensitivity of the sensor (which decreases specificity and may trigger a false positive on pollen or dust), but sampling itself. Air flows, testing, reset times, false negatives and positives, discriminating live from dead agents, networking sensors together to develop a clear, coherent picture of the environment of interest are all challenges.

One intriguing approach to biosensors is coupling immortalized rat brain cells onto a computer chip, and monitoring the electrical activity of the cell.¹² If the cell dies, this “canary on a chip” may provide warning that it has been exposed to a noxious agent. The

¹¹ Dr. Randy Curry. “Electro Technologies to Counter Biological Terrorism” in *Proceedings Report: Countering Biological Terrorism*, Arlington, VA. Potomac Institute for Policy Studies, August 1997.

¹² Robert Ackerman. “Sensor Development Races Biological Warfare Threat,” in *Signal*, December 1997.

advantage of this approach is that it works against both expected and unknown threats. One of the problems with it is that the device requires sterile fluid to pass over the neurons to provide nutrients and take away waste. Biosensors that offer the most information are mass spectrometers, but they are usually bulky and complex. However, Johns Hopkins University Applied Physics Laboratory has one now that is suitcase size and very promising. The field of biosensors is bursting with activity now, with many competitive approaches that we will not explore further here, but that are fascinating and important work.

The Defense Science Board has recommended establishing an information sharing network to focus on countering WMD terrorism. This will require wrapping and mediating disparate data sources, enabling natural language queries to data bases that can be translated into machine readable code by intelligent software agents with domain knowledge, and multi-level security, all of which are currently being worked hard for other applications, with fully practical systems still being pursued.

The Institute was enthused about the DSB recommendation to develop Combating WMD Counterterrorism Computer “Associate” for Force Protection. ‘Associate’ technology codes human expertise about a domain of interest (e.g., counterterrorism) and establishes links to information sources for that domain at an “anchor desk” or in a distributed fashion through the Internet. The ‘Associate’ computer can then assist a human novice to perform like an expert in the field, by leading him or her through a series of steps (as the original expert would approach that type of problem) and assist in answering the questions raised. Associate technology has been developed in the past, e.g., Pilot’s Associate which aided fighter pilots with situational awareness at high subsonic speeds, by performing many of the routine tasks needed to fly the aircraft and issuing warning of threats. If a quality Associate system to counter biological terrorism could be built for the military, the Institute would like to see it be modified for civilian application, and proliferated to localities to use in assessing their areas for vulnerabilities to WMD terrorism, assisting in wargames or training exercises, and being available if an actual attack took place.

Advanced Medical Countermeasures

One way to gain the initiative in countering biological terrorism is through advanced medical countermeasures. The US needs a strategy to leverage its asymmetrical advantage in advanced biotechnology to overcome the asymmetrical national security threat posed by biological agents. Currently, the specificity of the threat agent gives an advantage to the attacker. If he knows the Government has stockpiled Ciprofloxacin, for instance, to counteract anthrax infections (as the US did before the Gulf War), he could make his strain of anthrax resistant to that particular antibiotic (for instance, by dosing his sample culture with sublethal amounts of Ciprofloxacin before he reproduces it for dissemination). Similarly, vaccinations have limitations as the mainstay of a defense strategy. They need to be administered well in advance, so that the host has ample time to make sufficient antibodies to overcome disease. They can be overwhelmed by massive exposure to the threat agent. There are limits to the number of diseases one can be inoculated against.

There is a current controversy over the anthrax vaccine scheduled to be administered to US military personnel. Laboratory testing of tissues from Sverdlovsk victims indicate multiple strains of anthrax. The US Army says its vaccine is based on a small protein which is vital to all (165 identified thus far) strains of anthrax. The Army currently has seven million doses of vaccine made, including one million bottled and ready for use¹³. If the old Soviet Union had a genetically engineered “hot strain” of anthrax, it might be available to historical Soviet clients. Russian scientists reported several months ago in the British Journal *Vaccine* that they have made a strain of anthrax resistant to immunization. It has been reported that as recently as 1995, Russia has made business deals with Iraq for restricted biotechnology equipment, including a very large capacity fermenter (ostensibly to make animal feed).¹⁴ This indicates that vaccination may not be a totally effective way of preventing infection by anthrax, if more sophisticated forms of the agent are used.

For a more long term approach to neutralizing biological threats, it may be attractive to develop means to combat the effects of infection, rather than the threat agent itself. With anthrax, for instance, it is the secreted toxins that kill, rather than a direct effect of the pathogen itself. Advanced medical countermeasures could conceivably-- at some point-- develop an antidote to anthrax such that the human host could be colonized by the agent, and still have normal functioning (by interfering in the elicitation of cytotoxins from infected macrophages, or by blocking preferred toxin binding sites).¹⁵

¹³ *New York Times*, February 3, 1998.

¹⁴ R. Jeffrey Smith. “Did Russia Sell Iraq Germ Warfare Equipment?” *Washington Post*, February 12, 1998, p. A1, B34.

¹⁵ Dr. H. Lee Buchanan, *Proceedings of Potomac Institute Conference on Countering Biological Terrorism*, p.33.

Another approach is to engineer artificial receptors for threat pathogens to act as molecular “decoys,” mitigating the pathogen effects. There is a prospect of being able to counteract generic threats, rather than developing specific antidotes for each particular threat. In this manner, it is conceivable that by leveraging an asymmetric US advantage, advanced biotechnology, US defensive medical capabilities can be made to outpace threat offensive infection capabilities.

A promising example of an advanced medical countermeasure is provided by Dr. Ronald Taylor, a physical chemist at the University of Virginia, who has “hooked” viral receptors to the common red blood cell, and injected it into infected monkeys. Viral particles attached to the treated blood cells and were removed normally from the body. They did not clog the animal capillaries, and the monkeys showed no ill effects, and no measurable viral infection afterwards. The possibility of such chemotherapy against a virus is emblematic of the kind of advanced medical countermeasure the US and others need. Current antiviral agents- the one broad spectrum one is Ribavirin- are only moderately successful, and others such as amantadine, acyclovir, and azidothymidine are useful against only particular strains of virus (according to the *US Army Handbook on Medical Aspects of NBC Defensive Operations*). If the UVA approach proves safe and effective for humans in further trials (historically, most developmental drugs fail in human tests), it would significantly increase confidence against a catastrophic viral attack.

The most advanced drug research and development capabilities must be energized to perform required research to counter biological terrorism. This expertise is found largely in universities, and in small innovative biotech companies that are often startups from university personnel. The Government can stimulate research at this level with relatively modest investments. Once novel approaches have shown promise in the laboratory, they may underlay a more commercial exploitation. According to merchant bank Burrill and Company, US biotech firms raised more than \$11 billion in 1997 to support advanced research and development. This came in the form of Initial Public Offerings, venture capital investments, strategic alliances and partnering with other firms, often large pharmaceutical developers, among other methods¹⁶. Partnering tripled in dollar value from 1996 to 1997. In this method of financing, typically progress payments are made to the smaller innovative company upon achievement of technical milestones along the way to a commercial product, with an agreement for the larger firm to market the product, and pay royalties to the originators.

It is also interesting to note potential New Drug Applications (NDAs) for 1998. Some of them, like MedImmune’s treatment for respiratory syncytial virus in infants, seem to have a fairly small target population, providing encouragement that some drugs are being developed for even limited markets¹⁷. Other expected NDAs show possible

¹⁶ “Burrill and Company Announces 1997 Biotech Industry Analysis,” press release, Burrill and Company, December 31, 1997.

¹⁷ Ibid.

application to countering biological terrorism. They include Baxter's blood substitute and Aviron's nasal flu vaccine¹⁸.

Conducting most original research in open university and small commercial company settings has an added benefit. The public can be reassured that no inappropriate biological weapons research is being carried out in secret. Many of those least disposed to give the Government the benefit of the doubt in biological research often work at universities themselves. They may be more comfortable knowing those who perform the research, and can verify that it is being conducted in an appropriate way. In this regard, President Clinton announced in his State of the Union message that he supports, and will work to draft language by the end of 1998, to enforce the Biological Weapons Convention. This is a very encouraging sign, and the kind of visits outlined in the Administration's white paper on this topic appear to not place too onerous a burden on legitimate drug researchers. (However, as we have seen from lack of success of the intrusive inspection of Iraq, it is virtually impossible to verify BWC. Although the President characterized it as enforcement, the methods he briefly outlined appear to be more in line with the continuation of development of confidence building measures, which may be helpful, if not true verification itself).

A dual use (commercial-military) must be formulated to develop vital new drugs quickly. As stated, these drugs are ideally to have broad effects to neutralize the greatest number of potential threats possible, in line with the campaign to regain the initiative from the terrorists. This strategy also supports the dual use approach. These drugs should protect Americans against naturally occurring outbreaks of disease, as well as intentional releases. Therefore, these drugs may have significant commercial potential. Pharmaceutical companies may sponsor development of some important defense related drugs, if they believe there is also a civilian market. Those drugs that show promise in initial development should be handed off rapidly to commercial companies, if they will serve as champions to get the products to market. This is a long process that involves generation and review of pharmacology and toxicology data; making an Investigational New Drug (IND) application; protocol design and development; conduct and preparation of preclinical and clinical studies for NDA; etc.

There are currently several vaccines and medications that the military believes would be useful in countering biological attacks, but are not FDA approved. These are INDs, which require informed consent, as well as individual approval from the FDA. The FDA relaxed this requirement during the run up to the Gulf War, and now various individuals and groups are complaining that the use of experimental drugs without informed consent may be responsible for, or have contributed to, their Gulf War illness. The FDA is accepting comments now on this decision, with a view to drafting a new policy for emergency use of IND drugs. Even if this new policy is liberal, the terms of IND use, when human exposure to selected threats is extremely limited, and human testing would be unethical, highlight the limitations of the IND drug approach. Certainly,

¹⁸ Ibid.

meetings should be held with FDA to try to work out an approach for meaningful improvement and certification. Even so, stockpiling such drugs for use in a civilian emergency would also have the added risk of drug interaction complications, effects on the immuno-compromised, elderly and young; and the fact that the general population is generally less healthy to begin with compared to military service personnel.

If a drug targets a particular military-type threat, but has little commercial potential, a different approach is needed. There the recent acquisition by DoD of vaccines is instructive. A competition was held to supply drugs with long shelf lives. DoD will acquire these over time, and have a stockpile ready if needed. If new drugs can be developed that have narrowly military (or counter-terror) utility, they should be engineered to have long shelf lives if possible, in order to facilitate protracted buyouts. (In judging potential markets, DoD should consider that DoD may be called upon to share existing stockpiles with US civilians in the result of a terror attack. In addition, supplies will also likely be needed for coalition partners and local civilian support personnel and allied civilians in the event of a regional contingency abroad against biologically equipped adversary)¹⁹. Having this potentially large captive market for even a narrow-application drug over time may well induce established commercial firms to make the business decision to invest in supporting drug development over time, once they have been proven in principle to work and DoD is committed to their development.

To achieve this vision, a strategy has to be formulated to not only develop these advanced drugs, but to quickly make them available in the marketplace, fully approved by the Government. This process has, in the past, often taken years (10) and cost significant sums (\$1 billion+). Fortunately, the FDA has adopted a somewhat more streamlined drug approval process that may lessen that aspect of the burden. After three years of debate and consideration, the FDA Modernization Act of 1997 enacts changes in the way that the Agency regulates medicines and reauthorizes the Prescription Drug and User Fee Act (PDUFA) for five more years. Under PDUFA, companies may pay additional fees to underwrite testing of their drug on a priority basis. As part of a coherent Government strategy, drugs that are identified by the Department of Defense as requirements could receive priority in the expedited approval process. Funds from the increases in the National Institutes of Health budget for new drug development could be allocated to the clinical and other trials of DoD endorsed drugs to meet National needs (in line with the intent of the Congress and Administration to obtain important new drugs quickly).

The Institute's initial study pointed up the key role that the DoD may play in countering biological terrorism. The Quadrennial Defense Review and the DSB report both state clearly that defense of the homeland is a core DoD mission. However, even if that general principle is not fully embraced operationally by DoD, it is still pursuing missions with directly related technological bases, including Force Protection. The Institute considers that DoD will invest to create solutions to technical approaches for

¹⁹ Brad Roberts and Victor Utgoff, "Coalition Warfare Against WMD Foes," *Comparative Strategy*, Fall 1997 develops well critical issues in this regard.

countering military biological and other attacks. Once proven in principle, the most promising ones may be transitioned to the civilian world (perhaps through FEMA) and made available more widely to help protect American civilians. Once appropriate equipment is type qualified, it must be approved for use commercially (as by OSHA). The Government could list such equipment, and make it available for purchase at volume discounts by states and localities that desire and are able to do so. DoD would pay for non-recurring engineering and qualification expenses (thus reducing the development costs that would otherwise need recoupment in the commercial price structure), but would not be obligated to acquire equipment for use by localities, a potentially overwhelming financial burden. Similarly, FEMA could acquire limited sets of emergency equipment and distribute it to its regional centers for use in an emergency, without each state and locality needing to buy it. The first step is to review existing and planned DoD capabilities with a view to identifying the most promising assets to transition to civilian emergency use, and then developing an affordable approach to proliferating those assets.

The US DoD has a number of ongoing projects that would help in providing additional protection against biological terrorism. Some key ones follow.

- The Directorate of Military Support (DOMS) is currently making 65+ recommendations (in response to Secretary Cohen's reorganization of the Office of Secretary of Defense) for ways DoD can move to increase preparedness for countering WMD attacks.
- The 911-Bio Advanced Concept Technology Demonstration, recently completed, to affect cooperation among DoD assets for enhanced consequence management, including the Fiber Optic Waveguide biological agent identifier and the Spincon and BICC aerosol collector/concentrators, and their applicability to civil consequence management. The Airfield and Port protection ACTD also has applicability to civilian wide area bio defense.
- Atlantic Command is responsible for supplying forces in CONUS for military support to civil authorities following a WMD emergency once DoD is involved. ACOM also is the proposed the location of Force Protection Test Bed and the Military Operations Other Than War Simulation and Training facility. The possibility of expanding and integrating those assets to perform simulation and training to counter WMD terrorism should be exploited. For instance, advanced distributed simulation could be employed by the Government to evaluate the tradeoffs between individual and collective protective equipment in contaminated environments, and other such detailed questions that need to be satisfactorily addressed to support detailed planning to counter WMD terrorism in an urban environment. Once the military sorts out key questions for its force protection role, it could extend them to civil applications in cooperation with FEMA as appropriate.
- The DoD routinely supplies surplus military equipment to the Public Health Service National Disaster Medical System. This cooperation should be reviewed and may

serve as an extensible model of ways in which excess DoD equipment may be made available to states and localities for countering WMD terrorism.

SUMMARY

The US and West need to be more aware of the new, asymmetric strategic environment and its implications for national security. The threat of biological terrorism needs to be better characterized, permitting a sober and informed debate, and providing a compelling rationale for the allocation of resources. Promising new medical and non-medical countermeasures need to be identified and developed to counter the biological threat. In particular, the significant Western advantage in biotechnology should be leveraged to overcome the most likely threat pathogens. In addition, a feasibility assessment should be made of a potentially promising approach to combating biological terrorism in subway systems identified by the Institute. In general, although the difficulties of developing and fielding advanced technologies to counter biological terrorism are extremely challenging, we also believe that, in combination with effective policy innovations, several show great promise to help significantly reduce this serious threat over time.

Potomac Institute for Policy Studies' Overview

The Potomac Institute for Policy Studies is a not-for-profit organization formed in 1994 to develop and supply non-partisan analysis of technology and technology policy to leaders in government, business, and academia. As our logo suggests, the Institute reflects the summation of the effects of technology on society, from business to governing. Because of these combined effects, government technology policy will have enormous consequences for our nation's growth and security at a time when traditional government institutions are in transition.

The Potomac Institute for Policy Studies was developed independent of any federal or state agency, and can therefore conduct unbiased inquiries into issues that might otherwise be difficult to access. The loopholes and bureaucratic red tape that so frequently characterize "business as usual" in Washington can be sidestepped with such an organization, enabling results to be provided with greater expediency and autonomy. Since the Institute is not aligned politically with any party, it is a natural forum for open and unencumbered consideration of all options. In this manner, policy recommendations and evaluations are ensured to be the best conceivable, without having to satisfy a constituency. In addition, by virtue of being a non-profit organization, counsel will be made on the basis of merit, not funds.

The unpredictability of the dynamic and interdependent world in which we live increases the need for cutting edge technologies and strategies. The focus of the Institute is the study of these types of technology and their impact on American society. A combination of the most advanced resources and most highly regarded experts in the fields of policy and innovation make the Institute an important player in the maintenance of our nation's prosperity. The Institute has the potential to affect real changes in the general conception of technology and its role in the global community.

The Potomac Institute for Policy Studies is committed to providing an environment of analytic excellence to serve as a forum for debate regarding tomorrow's technology and security needs. By gathering noted and emerging experts in policy, economic, scientific and defense related areas, the Institute strives to go beyond analysis of critical areas to development of options responsive to future challenges.

The Potomac Institute engages in the study and research of the most demanding technology and technology policy questions facing our government and society. The studies and analyses are presented in a variety of formats, principally as reports and briefings requested of the Institute. Policy point papers and periodicals covering both broad policy issues and detailed information on specific topics are typical as well. The output of the Institute is not limited to results of the particular research or study, but also includes the value of the policy discussion itself. Meaningful technology policy finds use and application in our society, and that can only occur through informed public debate and discussion. The Institute is dedicated to initiating, mediating, and participating in those public policy forums.

The Institute continues to staff itself with a mixture of noted and emerging experts in a variety of disciplines in order to consistently provide new information to existing or

standard issues and analyses. The combination of leaders from business and government backgrounds alike creates an environment that promotes analytical development and exchange while simultaneously promoting awareness, for both private and public audiences, of the issues and of new options and potential solutions for technology policy challenges.

The Potomac Institute for Policy Studies is governed primarily by a Board of Directors responsible for overseeing policy and planning for the Institute. This board also serves as a decision-making body regarding the implementation of ongoing programs, specific studies, projects, and the development of the Institute Councils.

A Board of Regents aids the Board of Directors in their task of determining the strategic directions for the Potomac Institute. The Board of Regents consists of distinguished individuals who possess unique experience and insight and who have agreed to provide counsel, guidance, and support for the Institute for a term of three years. Although the Regents' primary focus is support and guidance for the Board of Directors, individual Regents are encouraged to work with the Officers and Fellows of the Institute to develop vibrant and successful research and study areas.

The Potomac Institute is very proud of the additional guidance and support of a number of highly regarded and exceptional individuals, among them Members of Congress, Senior Administration Officials, and leaders in private industry. The Institute is a more experienced, professional, and successful entity as a result of their assistance.

- ⊂ **David W. Siegrist- Study Director. *Research Fellow, Potomac Institute for Policy Studies.*** MS in Management, National-Louis University, MA in Government, Georgetown University.

David W. Siegrist had lead technical responsibility for the recent successful study on Countering Biological Terrorism sponsored by the Smith Richardson Foundation. He is a former Principal Staff Member of BDM Federal, a professional services consulting firm. He has been a long-term consultant to the Defense Department, where he analyzed a broad range of national security technology issues. Among other efforts, he was a lead analyst for the Joint Program Steering Group in Military Operations Other Than War/Law Enforcement, which is resident at DARPA. Mr. Siegrist conducted a study at the Army War College to prioritize requirements for MOOTW training to inform the development of interactive simulation trainers for military and law enforcement personnel. He also supported the Information Technology project of MOOTW/LE, including identifying data sharing needs and advanced technologies for information distribution among Government agencies. Mr. Siegrist is also a former National Strategy Public Policy Fellow of Georgetown University and is currently an adjunct faculty member of Georgetown University, where he teaches courses in national security and intelligence. Mr. Siegrist has been published in the *Journal of Defense Research*, has briefed the recent Defense Science Board on Transnational Threats, and has been interviewed on the subject of biological terrorism on television and by Nature magazine. He was the study coordinator for the initial Potomac Institute study on countering biological terrorism, and the moderator of the conference the Institute held on that topic. He was recently invited to Israel to report on the Institute's research at an international conference on "Threats of the Technological Age."