

Biodefense for the 21st Century

"Bioterrorism is a real threat to our country. It's a threat to every nation that loves freedom. Terrorist groups seek biological weapons; we know some rogue states already have them....It's important that we confront these real threats to our country and prepare for future emergencies."

President George W. Bush June 12, 2002

"Armed with a single vial of a biological agent, small groups of fanatics, or failing states, could gain the power to threaten great nations, threaten the world peace. America, and the entire civilized world, will face this threat for decades to come. We must confront the danger with open eyes, and unbending purpose."

President Bush February 11, 2004

Biological weapons in the possession of hostile states or terrorists pose unique and grave threats to the safety and security of the United States and our allies.

Biological weapons attacks could cause catastrophic harm. They could inflict widespread injury and result in massive casualties and economic disruption. Bioterror attacks could mimic naturally-occurring disease, potentially delaying recognition of an attack and creating uncertainty about whether one has even occurred. An attacker may thus believe that he could escape identification and capture or retaliation.

Biological weapons attacks could be mounted either inside or outside the United States and, because some biological weapons agents are contagious, the effects of an initial attack could spread widely. Disease outbreaks, whether natural or deliberate, respect no geographic or political borders.

Preventing and controlling future biological weapons threats will be even more challenging. Advances in biotechnology and life sciences -- including the spread of expertise to create modified or novel organisms -- present the prospect of new toxins, live agents, and bioregulators that would require new detection methods, preventive measures, and treatments. These trends increase the risk for surprise. Anticipating such threats through intelligence efforts is made more difficult by the dual-use nature of biological technologies and infrastructure, and the likelihood that adversaries will use denial and deception to conceal their illicit activities. The stakes could not be higher for our Nation. Attacks with biological weapons could:

- Cause catastrophic numbers of acute casualties, long-term disease and disability, psychological trauma, and mass panic;
- Disrupt critical sectors of our economy and the day-to-day lives of Americans; and
- Create cascading international effects by disrupting and damaging international trade relationships, potentially globalizing the impacts of an attack on United States soil.

Fortunately, the United States possesses formidable capabilities to mount credible biodefenses. We have mobilized our unrivaled biomedical research infrastructure and expanded our international research relationships. In addition, we have an established medical and public health infrastructure that is being revitalized and expanded. These capabilities provide a critical foundation on which to build improved and comprehensive biodefenses.

The United States has pursued aggressively a broad range of programs and capabilities to confront the biological weapons threat. These actions, taken together, represent an extraordinary level of effort by any measure. Among our significant accomplishments, we have:

- Expanded international efforts to keep dangerous biological materials out of the hands of terrorists;
- Launched the Proliferation Security Initiative to stem the trafficking in weapons of mass destruction (WMD), including biological weapons;

- Established the BioWatch program, a network of environmental sensors to detect biological weapons attacks against major cities in the United States;
- Initiated new programs to secure and defend our agriculture and food systems against biological contamination;
- Increased funding for bioterrorism research within the Department of Health and Human Services by thirty-fold;
- Expanded the Strategic National Stockpile of medicines for treating victims of bioterror attacks, ensuring that the stockpile's push packages can be anywhere in the United States within 12 hours;
- Stockpiled enough smallpox vaccine for every American, and vaccinated over 450,000 members of the armed services;
- Launched and funded Project BioShield to speed the development and acquisition of new medical countermeasures against biological weapons;
- Provided Federal funds to improve the capacities of state and local health systems to detect, diagnose, prevent, and respond to biological weapons attacks; and
- Worked with the international community to strengthen global, regional and national programs to prevent, detect, and respond to biological weapons attacks.

Building on these accomplishments, we conducted a comprehensive evaluation of our biological defense capabilities to identify future priorities and actions to support them. The results of that study provide a blueprint for our future biodefense program, Biodefense for the 21st Century, that fully integrates the sustained efforts of the national and homeland security, medical, public health, intelligence, diplomatic, and law enforcement communities.

Specific direction to departments and agencies to carry out this biodefense program is contained in a classified version of this directive.

BIODEFENSE FOR THE 21ST CENTURY

The United States will continue to use all means necessary to prevent, protect against, and mitigate biological weapons attacks perpetrated against our homeland and our global interests. Defending against biological weapons attacks requires us to further sharpen our policy, coordination, and planning to integrate the biodefense capabilities that reside at the Federal, state, local, and private sector levels. We must further strengthen the strong international dimension to our efforts, which seeks close international cooperation and coordination with friends and allies to maximize our capabilities for mutual defense against biological weapons threats.

While the public health philosophy of the 20th Century - emphasizing prevention - is ideal for addressing natural disease outbreaks, it is not sufficient to confront 21st Century threats where adversaries may use biological weapons agents as part of a long-term campaign of aggression and terror. Health care providers and public health officers are among our first lines of defense. Therefore, we are building on the progress of the past three years to further improve the preparedness of our public health and medical systems to address current and future BW threats and to respond with greater speed and flexibility to multiple or repetitive attacks.

Private, local, and state capabilities are being augmented by and coordinated with Federal assets, to provide layered defenses against biological weapons attacks. These improvements will complement and enhance our defense against emerging or reemerging natural infectious diseases.

The traditional approach toward protecting agriculture, food, and water - focusing on the natural or unintentional introduction of a disease -- also is being greatly strengthened by focused efforts to address

current and anticipated future biological weapons threats that may be deliberate, multiple, and repetitive.

Finally, we are continuing to adapt United States military forces to meet the biological weapons challenge. We have long recognized that adversaries may seek biological weapons to overcome our conventional strength and to deter us from responding to aggression. A demonstrated military capability to defend against biological weapons and other WMD strengthens our forward military presence in regions vital to United States security, promotes deterrence, and provides reassurance to critical friends and allies. The Department of Defense will continue to ensure that United States military forces can operate effectively in the face of biological weapons attacks, and that our troops and our critical domestic and overseas installations are effectively protected against such threats.

PILLARS OF OUR BIODEFENSE PROGRAM

The essential pillars of our national biodefense program are: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

Successful implementation of our program requires optimizing critical cross-cutting functions such as: information management and communications; research development and acquisition; creation and maintenance of needed biodefense infrastructure, including the human capital to support it; public preparedness; and strengthened bilateral, multilateral, and international cooperation.

National biodefense preparedness and response requires the involvement of a wide range of Federal departments and agencies. The Secretary of Homeland Security is the principal Federal official for domestic incident management and is responsible for coordinating domestic Federal operations to prepare for, respond to, and recover from biological weapons attacks. The Secretary of Homeland Security coordinates, as appropriate, with the heads of other Federal departments and agencies, to effectively accomplish this mission.

The Secretary of State is the principal Federal officer responsible for international terrorist incidents that take place outside the U.S. territory, including United States support for foreign consequence management and coordinates, as appropriate, with heads of other Federal departments and agencies, to effectively accomplish this mission. When requested by the Secretary of State, and approved by the Secretary of Defense, the Department of Defense will support United States foreign consequence management operations, as appropriate.

The following sections describe our aims and objectives for further progress under each of the pillars of our national biodefense program, as well as highlight key roles played by Federal departments and agencies.

Threat Awareness

Biological Warfare Related Intelligence

Timely, accurate, and relevant intelligence enables all aspects of our national biodefense program. Despite the inherent challenges of identifying and characterizing biological weapons programs and anticipating biological attacks, we are improving the Intelligence Community's ability to collect, analyze, and disseminate intelligence. We are increasing the resources dedicated to these missions and adopting more aggressive approaches for accomplishing them. Among our many initiatives, we are continuing to develop more forward-looking analyses, to include Red Teaming efforts, to understand new scientific trends that may be exploited by our adversaries to develop biological weapons and to help position intelligence collectors ahead of the problem.

Assessments

Another critical element of our biodefense policy is the development of periodic assessments of the evolving biological weapons threat. First, the United States requires a continuous, formal process for conducting routine capabilities assessments to guide prioritization of our on-going investments in biodefense-related research, development, planning, and preparedness. These assessments will be

tailored to meet the requirements in each of these areas. Second, the United States requires a periodic senior-level policy net assessment that evaluates progress in implementing this policy, identifies continuing gaps or vulnerabilities in our biodefense posture, and makes recommendations for re-balancing and refining investments among the pillars of our overall biodefense policy. The Department of Homeland Security, in coordination with other appropriate Federal departments and agencies, will be responsible for conducting these assessments.

Anticipation of Future Threats

The proliferation of biological materials, technologies, and expertise increases the potential for adversaries to design a pathogen to evade our existing medical and non-medical countermeasures. To address this challenge, we are taking advantage of these same technologies to ensure that we can anticipate and prepare for the emergence of this threat. We are building the flexibility and speed to characterize such agents, assess existing defenses, and rapidly develop safe and effective countermeasures. In addition, we must guard against the spread of potentially infectious agents from beyond our borders. We are strengthening the ability of our medical, public health, agricultural, defense, law enforcement, diplomatic, environmental, and transportation infrastructures to recognize and confront such threats and to contain their impact. The Department of Health and Human Services, in coordination with other appropriate Federal departments and agencies, is working to ensure an integrated and focused national effort to anticipate and respond to emerging biological weapons threats.

Prevention and Protection

Proactive Prevention

Preventing biological weapons attacks is by far the most cost-effective approach to biodefense. Prevention requires the continuation and expansion of current multilateral initiatives to limit the access of agents, technology, and know-how to countries, groups, or individuals seeking to develop, produce, and use these agents.

To address this challenge, we are further enhancing diplomacy, arms control, law enforcement, multilateral export controls, and threat reduction assistance that impede adversaries seeking biological weapons capabilities. Federal departments and agencies with existing authorities will continue to expand threat reduction assistance programs aimed at preventing the proliferation of biological weapons expertise. We will continue to build international coalitions to support these efforts, encouraging increased political and financial support for nonproliferation and threat reduction programs. We will also continue to expand efforts to control access and use of pathogens to strengthen security and prevention.

The National Strategy to Combat Weapons of Mass Destruction, released in December 2002, places special emphasis on the need for proactive steps to confront WMD threats. Consistent with this approach, we have improved and will further improve our ability to detect and destroy an adversary's biological weapons assets before they can be used. We are also further expanding existing capabilities to interdict enabling technologies and materials, including through the Proliferation Security Initiative. Additionally, we are working to improve supporting intelligence capabilities to provide timely and accurate information to support proactive prevention.

Responsibilities for proactive prevention are wide-ranging, with the Department of State, Department of Defense, Department of Justice, and the Intelligence Community playing critical roles in our overall government-wide effort.

Critical Infrastructure Protection

Protecting our critical infrastructure from the effects of biological weapons attacks is a priority. A biological weapons attack might deny us access to essential facilities and response capabilities. Therefore, we are working to improve the survivability and ensure the continuity and restoration of operations of critical infrastructure sectors following biological weapons attacks. Assessing the vulnerability of this infrastructure, particularly the medical, public health, food, water, energy, agricultural, and transportation

sectors, is the focus of current efforts. The Department of Homeland Security, in coordination with other appropriate Federal departments and agencies, leads these efforts, which include developing and deploying biodetection technologies and decontamination methodologies.

Surveillance and Detection

Attack Warning

Early warning, detection, or recognition of biological weapons attacks to permit a timely response to mitigate their consequences is an essential component of biodefense. Through the President's recently proposed biosurveillance initiative, the United States is working to develop an integrated and comprehensive attack warning system to rapidly recognize and characterize the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment. Creating a national bioawareness system will permit the recognition of a biological attack at the earliest possible moment and permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption. Such a system will be built upon and reinforce existing Federal, state, local, and international surveillance systems. The Department of Homeland Security, in coordination with other appropriate Federal departments and agencies, integrates these efforts.

Attribution

Deterrence is the historical cornerstone of our defense, and attribution -- the identification of the perpetrator as well as method of attack -- forms the foundation upon which deterrence rests. Biological weapons, however, lend themselves to covert or clandestine attacks that could permit the perpetrator to remain anonymous. We are enhancing our deterrence posture by improving attribution capabilities. We are improving our capability to perform technical forensic analysis and to assimilate all-source information to enable attribution assessments. We have created and designated the National Bioforensic Analysis Center of the National Biodefense Analysis and Countermeasure Center, under the Department of Homeland Security, as the lead Federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials recovered following a biological attack in support of the appropriate lead Federal agency.

Response and Recovery

Once a biological weapons attack is detected, the speed and coordination of the Federal, state, local, private sector, and international response will be critical in mitigating the lethal, medical, psychological, and economic consequences of such attacks. Responses to biological weapons attacks depend on pre-attack planning and preparedness, capabilities to treat casualties, risk communications, physical control measures, medical countermeasures, and decontamination capabilities.

Response Planning

A biological response annex is being drafted as part of our National Response Plan (NRP). We are catalyzing the development of state and local plans that are consistent with the NRP and ensure a seamless coordinated effort. Capabilities required for response and mitigation against biological attacks will be based on interagency-agreed scenarios that are derived from plausible threat assessments. These plans will be regularly tested as part of Federal, state, local, and international exercises. The Department of Homeland Security, in coordination with other appropriate Federal departments and agencies, is developing comprehensive plans that provide for seamless, coordinated Federal, state, local, and international responses to a biological attack.

Mass Casualty Care

Following a biological weapons attack, all necessary means must be rapidly brought to bear to prevent loss of life, illness, psychological trauma, and to contain the spread of potentially contagious diseases. Provision of timely preventive treatments such as antibiotics or vaccines saves lives, protects scarce medical capabilities, preserves social order, and is cost effective.

The Administration is working closely with state and local public health officials to strengthen plans to swiftly distribute needed medical countermeasures. Moreover, we are working to expand and, where needed, create new Federal, state, and local medical and public health capabilities for all-hazard mass casualty care.

The Department of Health and Human Services, in coordination with other appropriate Federal departments and agencies, is the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the state and local medical and public health response to mass casualty events. For those mass casualty incidents that require parallel deployment of Federal assets in other functional areas such as transportation or law enforcement, the Department of Homeland Security will coordinate the overall Federal response in accordance with its statutory authorities for domestic incident management. Under certain circumstances, the Department of Veterans Affairs and the Department of Defense, given their specialized expertise and experience, may be called upon to play important supporting roles in mass casualty care.

Risk Communication

A critical adjunct capability to mass casualty care is effective risk communication. Timely communications with the general public and the medical and public health communities can significantly influence the success of response efforts, including health- and life-sustaining interventions. Efforts will be made to develop communication strategies, plans, products, and channels to reach all segments of our society, including those with physical or language limitations. These efforts will ensure timely domestic and international dissemination of information that educates and reassures the general public and relevant professional sectors before, during, and after an attack or other public health emergency.

The Department of Homeland Security, in coordination with other appropriate Federal departments and agencies, is developing comprehensive coordinated risk communication strategies to facilitate emergency preparedness for biological weapons attacks. This includes travel and citizen advisories, international coordination and communication, and response and recovery communications in the event of a large-scale biological attack.

Medical Countermeasure Development

Development and deployment of safe, effective medical countermeasures against biological weapons agents of concern remains an urgent priority. The National Institutes of Health (NIH), under the direction of the Department of Health and Human Services, is working with the Department of Homeland Security, the Department of Defense, and other agencies to shape and execute an aggressive research program to develop better medical countermeasures. NIH's work increasingly will reflect the potential for novel or genetically engineered biological weapons agents and possible scenarios that require providing broad-spectrum coverage against a range of possible biological threats to prevent illness even after exposure. Additionally, we have begun construction of new labs. We are striving to assure the nation has the infrastructure required to test and evaluate existing, proposed, or promising countermeasures, assess their safety and effectiveness, expedite their development, and ensure rapid licensure.

The Department of Health and Human Services, in coordination with other appropriate Federal departments and agencies, will continue to ensure the development and availability of sufficient quantities of safe and efficacious medical countermeasures to mitigate illness and death in the event of a biological weapons attack.

Decontamination

Recovering from a biological weapons attack may require significant decontamination and remediation activities. We are working to improve Federal capabilities to support states and localities in their efforts to rapidly assess, decontaminate, and return to pre-attack activities, and are developing standards and protocols for the most effective approaches for these activities.

The Administrator of the Environmental Protection Agency, in coordination with the Attorney General and

the Secretaries of Defense, Agriculture, Labor, Health and Human Services, and Homeland Security, is developing specific standards, protocols, and capabilities to address the risks of contamination following a biological weapons attack and developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities.