A Nation Unprepared:

Bioterrorism and Pandemic Response

by John B. Foley

n 2001, senior U.S. policymakers converged to participate in the still famous Dark Winter exercise. The exercise contemplated a covert, bioterrorist attack against the U.S. The scenario began with simultaneous attacks, involving smallpox, on shopping malls in 3 separate states, resulting in 3,000 people becoming infected. By the end of the exercise, 16,000 smallpox cases had been reported in 25 states, 1,000 people had died, the healthcare system could not meet the patient load, 10 countries were reporting smallpox outbreaks, and Canada and Mexico had closed their borders. The smallpox vaccine stockpile had been depleted, and new stocks would not be available for a month. States had imposed travel restrictions, and food supplies were dwindling. People were fleeing cities, and the economy was faltering.

Even in 2001, a bioterrorist attack was not simply the stuff of science fiction. Between 1970 and 1998, the U.S. recorded over 400 suspected terrorist activities involving chemical or biological agents. In the immediate aftermath of Dark Winter exercise, the U.S. grappled with the 2001 Amerithrax attack on government offices in Washington and subsequently opened the treasury's floodgates to address the shortfalls revealed both by the Dark Winter exercise and the Amerithrax attack. However, a decade and a half later, as the nation faced the 2014–2016 Ebola crisis, assessments of the U.S. government response led to a sobering conclusion: The U.S. still has not learned the lessons of Dark Winter.

Transporting Infected Persons

In the spring of 2014, the first reports of an Ebola outbreak in West Africa came from Guinea. The virus quickly spread throughout the West African countries of Sierra Leone, Liberia, Nigeria, Senegal, and Mali. Of the more than 10,000 people infected with the Ebola virus, more than half died. The initial response by the international community was viewed as a failure. President Obama declared the Ebola outbreak a top national security priority. What had been a distant public health crisis had now been elevated to a national security threat. Obama ordered U.S. troops to West Africa

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in September to provide humanitarian assistance. U.S. efforts in West Africa centered on containing the epidemic and limiting the spread of disease. The Department of Defense (DoD) spent almost \$400 million in its response support. The Ebola outbreak became the predominant news story, and bodies of Ebola victims lying in the streets greeted news watchers. The Centers for Disease Control and Prevention (CDC) assured the public that the U.S. healthcare system could deal with any outbreak.

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The U.S. military had worked with highly infectious agents like Ebola for many years. Treating highly infectious patients required the highest isolation standards. In 1978, the U.S. military developed a patient transport capsule that could safely contain an individual exposed to highly infectious diseases like Ebola. These isolation capsules were part of the Aeromedical Isolation and Special Medical Augmentation Response Team (AIT-SMART). An AIT-SMART team could transport one infected patient directly into a Biosafety Level 4 (BSL-4), the biosafety level at which the deadliest pathogens can be safely contained, and two such teams could be deployed simultaneously.3 Given the number of persons likely to be affected by any bioterrorist attack, the idea that this capability could be applied to a mass-infection scenario seems almost farcical. When AIT-SMART teams were retired in 2010 and replaced by U.S. Air Force Critical Care Air Transport Teams (CCQTs), patient capacity expanded from one to five ventilator patients or ten less-critical patients. Naturally, even this tenfold capability increase did nothing to address the mass-infection

problem.

Disease Recognition and Response Training

Even a limitless transportation capability is potentially useless unless infected persons can be properly identified. Ebola entered the U.S. hitchhiking in the living cells of an international traveler. The first reported U.S case of Ebola came on September 30, 2014 in Dallas. A man who had recently returned from Liberia became ill. A week later, he was dead. Two of the man's healthcare providers developed similar symptoms. Although they were treated and recovered, both lacked the requisite knowledge and training needed for isolating patients infected with such a deadly pathogen. Protective barrier requirements established for deadly pathogens such as Ebola were nonexistent. Personal protective equipment was inadequate. Isolation of the patient was done in a facility that was not equipped to contain the pathogen. So simple a matter as patient waste removal became a major bureaucratic challenge. Poorly executed coordination and communication between federal and local officials resulted in unnecessary delay in cleanup and disposal of hazardous waste from the victim's apartment. The victim's family was kept in quarantine by law enforcement. Compounding the various local miscues, the CDC itself was forced to revise its previously published guidelines and protocols for the treatment of Ebola patients. The CDC now assessed that it was possible to become infected from droplets up to three feet away.4

A subsequent case of Ebola was diagnosed in in a New York City healthcare worker who had returned from abroad. After several days in New York, he developed a fever, notified city health authorities, and was immediately put in isolation. The governors of New York and New Jersey responded by imposing 21 day quarantines on any medical workers returning from countries

affected with Ebola. Conflicts soon arose between the states and the federal government. The federal guidelines called for individuals to self-monitor for fever and regularly report their status to local health departments for 21 days. Reports circulated that people were afraid to ride the subway for fear of catching Ebola. Additional cases of Ebola infection were treated in specialized isolation facilities at Emory University Hospital, Nebraska Medical Center, and at the National Institutes of Health (NIH). By this point, Dr. Francis Collins, the Director of NIH, observed, "We need to take this current outbreak as a wake-up call. Diseases will come, and we have to be prepared, by investing in the public health infrastructure that keeps America safe."5

Following the Ebola crisis. subcommittees (Emergency Preparedness Response and Communications) of the House Committee on Homeland Security assembled to investigate U.S. preparedness for a biological attack. Representative Martha McSally (R-Arizona) raised concern that a terrorist organization could launch a bioterrorist attack against the U.S. homeland. She said, "The risk of a biological terrorist attack to America is an urgent and serious threat. A bio attack could cause illness, and even kill hundreds of thousands of people, overwhelm our public health capabilities and create significant economic, societal and political consequences. Our nation's capacity to prevent, respond to and mitigate the impacts of biological terror incidents is a top national priority."6

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The Interagency Problem

Remarkably, there is not a single official who ensures that all agencies of the federal

government work together on biodefense, even though at least five federal departments that have significant responsibilities in the event of a bioterrorist incident. A covert, bioterrorist attack would require a whole unity of effort response by the U.S. Presidential Decision Directive (PDD)-39 attempted to address this concern. PDD-39 specifies how federal agencies are to divide responsibilities among themselves with respect to weapons of mass destruction exercises and incidents.7 It assigns central roles to the Federal Bureau of Investigation (FBI) and Federal Emergency Management Agency (FEMA) in the federal response to any terrorist event that results in mass casualties—the FBI as the lead agency for crisis management and FEMA as the lead agency for consequence management

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of mass casualty events. However, epidemic crisis management is not something that the FBI does daily. Likewise, FEMA does not have the skill, the correct personnel, or the authority and responsibility to act as a trusted agent when it comes to coordinating the necessary public health response required to mitigate an epidemic. FEMA is structured to deal with things such as earthquakes, floods, hurricanes, and tornados involving mass casualties, but not events involving biohazards. Responsibility for planning, equipping, and training requirements likewise must be identified. However, PDD-39 does not address how the U.S. should prepare for a covert, biological event. It does not provide guidance on how to improve existing efforts that were in place or identify areas that could be improved. Moreover, because it states that agencies "will bear the costs of the participation

in terrorist incidents and counterterrorist operations, unless otherwise directed,"8 bureaucratic inertia and protectiveness of budgets serve to create a disincentive for interagency cooperation.

In an effort to move forward in a coordinated, unified fashion, President Obama named an Ebola "Czar"; however, the temporary nature of the positon lacked the authority or power to bring about change. This situation called for the designation of a single responsible federal official to coordinate authority and make executive decisions across the interagency with respect to the biodefense enterprise.

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Budgeting to Protect against Bioterrorism

The federal government does not lack funding to protect against bioterrorism as much, it would appear, as it lacks a coordinated investment strategy. The present piecemeal approach to biodefense preparedness opens the possibility to numerous acquisition problems, including duplication of purchases, over or underestimation of requirements, purchasing improper equipment, and mismanagement of inventory.

• The Department of Homeland Security (DHS) was appropriated \$47 million in supplemental funding to prepare for a pandemic. It spent this funding on personal protective equipment, research, and exercises. In 2014, an audit conducted by the DHS Inspector General found that DHS had not effectively managed pandemic personal protective equipment and antiviral

- medical countermeasures. DHS did not adequately conduct a needs assessment prior to purchasing personal protective equipment and medical countermeasures.¹⁰
- Following the 2001 anthrax letter attacks, Congress appropriated almost \$3 billion to counter biological threats against the populace. The appropriation included over \$1 billion to purchase antibiotics and vaccines as part of the Strategic National Stockpile (SNS). The CDC was tasked with determining the most probable and dangerous biological threat to the civil populace. The CDC used the following criteria set to make their determination:¹¹
 - Impact on public health based on death and illness.
 - Ease of delivery to a large population.
 The stability of the agent, ability to mass produce and distribute and the R₀, its potential for person-to-person transmission of the agent.
 - Public fear perception and potential civil disruption.
 - Special public health preparedness requirements based on stockpile requirements (vaccines), enhanced surveillance, or diagnostic needs.
- In 2002, Congress also earmarked \$1 billion for state-level public health system improvements.
- The Project BioShield Act of 2004 authorized the U.S. government to spend \$5.6 billion over 10 years to acquire medical counter measures.¹²

The biodefense enterprise budget witnessed a huge increase in funding from FY 2001 to FY 2014, with civilian biodefense funding totaling \$78.8 billion. Of this, \$64.93 billion went to programs that included both biodefense and non-biodefense lines of effort. The remaining \$13.89 billion went for programs which are

solely dedicated to biodefense.¹³ A closer look at the FY2001–FY2014 Civil Biodefense Funding shows that approximately \$80 billion was spent on biodefense from FY2001 through FY2014. The majority of those expenditures went toward multi-hazard programs, and only about 17 percent went toward biodefense as such.

Although the biodefense enterprise receives multiyear funding for some of its programs, it receives only annual appropriations for others. A case in point is Project BioShield. This annual appropriation approach stymies strategic planning and execution to prepare programs for such things as changing political priorities and continuing budget resolutions. Moreover, budgets for the biodefense enterprise are difficult to predict from year to year. For example, the CDC's FY2014 proposed budget was \$47.7 million less than its FY2013 budget. Three of the CDC's biodefense programs had significant reductions. The State and Local Preparedness and Response Capability, which includes the Public Health Emergency Preparedness (PHEP) cooperative agreement grant program, was reduced by \$8.2 million to \$658 million. PHEP provides funding for public health departments to upgrade their ability to respond to public health threats such as natural disasters, infectious diseases, and nuclear, biological, and chemical events. This was a 30 percent reduction from FY2002 funding. The SNS's funding was also reduced by \$38.4 million to \$510.3 million, and the CDC Preparedness and Response Capability would be reduced by \$1.1 million. Thus, enormous appropriations notwithstanding, a lack of a comprehensive investment plan, based on a strategic vision not subject to annual caprice, makes it impossible to determine if the biodefense enterprise is adequately funded.

A Strategic Approach

A lack of a strategic vision as to what exactly biodefense seeks to accomplish is the greatest barrier to the success of interagency efforts at biodefense. The old maxim that "defense does not win wars" should not be ignored by biodefense planners. History is replete with examples of strategies that circumvented known defenses. If the nation is well protected against, for example, anthrax or smallpox, an intelligent adversary would not attack with anthrax or smallpox when nature is replete with a wide range of pathogens that could be considered for use against humans. Novel viruses and new disease continue to emerge, and advances in biotechnology make it possible to manipulate how a virus behaves. Biological weapons programs, once only the domain of state-sponsored research organizations, are now within the reach of non-state actors. An individual with a graduate-level degree has

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all the tools and technologies to implement a sophisticated program to create a bioweapon.¹⁴ The costs associated with the setup and operation of facilities to explore, develop, and cultivate biological hazards are within the reach of well-funded terrorist organizations. A terrorist organization with several hundred thousand dollars, a dedicated group of graduate-level students, and a space of several hundred square meters could establish a small-scale biological weapons program.¹⁵

On the other hand, the U.S. government has made significant strides in biodefense. It has actively pursued efforts at the federal level and in concert with the states to deter, protect, and respond to a biological event. Funding has been appropriated to provide for the infrastructure, training, and equipping of local, state, and national responders. National-level exercises

have been conducted to test and refine local, state, and national level response.

The CDC has consolidated various bio surveillance programs into its National Electronic Surveillance System (NEEDS). This consolidation resulted in reducing confusion and easing the reporting process. All 50 states and the District of Columbia use a NEEDS-compatible system.¹⁶

The CDC has provided grants for states to upgrade their laboratories forensic capabilities. The Laboratory Response Network was set up to provide local and state laboratories a rapid confirmatory process of suspected pathogens. The CDC and NIH continue research efforts on vaccines against diseases that have the potential to be weaponized.

DoD hospitals, as well as the health facilities of the Veterans Affairs (VA), can be called upon in the event of a national emergency.¹⁷

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The Department of Justice (DOJ) has provided biological terrorism training to law enforcement personnel and first responders. DOJ has also provided grants to states and cities to purchase personal protective gear for law enforcement and first responders.

DHS has developed a strategy toward improving the health security of the nation. The National Health Security Strategy (NHSS), published in 2010, provides for a unified approach for improving the health security of the nation. This unified approach relies heavily on the collaborative efforts of government agencies, community organizations, private enterprise, and academia. The NHSS lines of effort focus on community resilience, public health emergency medical countermeasures, health situation awareness, and healthcare coalitions. Community

partners have made significant progress in health security improvement. There are now more than 24,000 members in the Hospital Preparedness Program. Of the nation's 6,340 hospitals, 5,288 are affiliated with the Hospital Preparedness Program.¹⁸ This consortium has significantly improved hospital to hospital and responder to hospital communication capabilities. Critical information regarding the availability of resource and beds can now track critical data when trying to determine where to route ambulances. These partnership programs have resulted in stronger state and local public health agencies. Federal preparedness grants from Department of Health and Human Services and FEMA have benefited states and local communities' ability to respond to a bioterror event.

The National Response Framework (NRF) incorporates plans from the interagency. These interagency plans become the supporting plans or operational supplements to the NRF. Even though the NRF takes an "all-hazards" approach to consequence management, it is intended to be sufficiently flexible to orient interagency efforts to respond even to a bioterror attack.

All 50 states have plans in place that provide a framework to respond to a biological event. All states have a SNS plan in place. These allencompassing plans detail the receipt, storage, and distribution of the SNS push packages. Some states that have either large metropolitan statistical areas or large cities have plans in place supporting the Cities Readiness Initiative. The Cities Readiness Initiative, located in 72 cities, provides coverage to roughly percent of the U.S. population.19 In important ways, therefore, federal investments have increased the country's ability to respond to a bioterrorists attack. Biodefense funding has provided states and local communities the means to improve their public health networks preparedness and response capabilities. First responders and law enforcement have been trained and equipped to respond to a bioterrorist event. State and local

emergency management planners have developed plans to mitigate a bioterrorist event.

Conclusion

In the final analysis, however, the U.S. government is still haunted by, and should give heed to, the principal lessons of Dark Winter:

- The nation still lacks sufficient drugs and vaccines to mitigate an epidemic—which it must have, if for no other reason than as a deterrent against the possibility of an informed adversary attacking with pathogens against which the U.S. is already protected.
- The nation's healthcare cadre is inadequately trained and equipped to confront a major bioattack.
- The nation's healthcare system lacks adequate surge capacity.
- Lines of authority across the interagency for responding to bioterrorism are ill-defined at best, and centralized leadership and coordinating authority is not firmly in place.
- Coordination efforts at all levels must thoroughly integrate medical expertise.
- Means for ensuring the accurate and timely dissemination of public information must be refined.

Failure to heed these lessons simply leaves the U.S. vulnerable, beyond what prudent risk management would suggest, to the threat of bioterrorism.

The U.S. has never had a bioterror attack that has resulted in an epidemic. The U.S. has had hundreds of suspected terrorist activities that have involved chemical or biological agents. The Anthrax attack mailings, coming just weeks after the attacks of 9/11, demonstrated how vulnerable the U.S. was to a bioterror attack. The federal response to the Anthrax attacks was so fraught with problems and ineptitude, it warranted the government's watch dog agency to proclaim that "the response was not only problematic but the response clearly indicated that the U.S. was not prepared for a terrorist biological attack." The world's largest outbreak of Ebola in West Africa gripped the world's attention and revealed troubling gaps and seams in federal bioterrorism response capabilities even though, despite collective miscues at all levels of government, only one fatality occurred.

The U.S. has conducted a massive effort to prepare the nation to respond to a bioterrorist event against several known weaponized pathogens. Billions of dollars have been spent on biodefense programs, but a very low percentage of those funds have gone toward the biodefense of the civil populace—the sole and proper object of biodefense in the first instance. Sir Ernest Rutherford is reputed to have once said, "we haven't the money, so we've got to think." It may be that no amount of money will adequately substitute for the imperative to think. In any case, instead of waiting for a real "dark winter" to occur, serious thinking—in a coordinated manner across the interagency—about the bioterrorism problem is much needed and long overdue. **IAJ**

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