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Executive Summary

The anthrax attacks in 2001 galvanized government action to advance national programs in biodefense research, drug and vaccine development, medical countermeasure (MCM) stockpiling, hospital preparedness, and a range of other biosecurity and biodefense initiatives. As a result, the United States currently has a much higher level of biopreparedness than it did prior to 2001. Yet, despite the progress made since 2001, a large-scale biological attack (or the immediate threat of such an attack) against one or more American cities would require additional and extraordinary national action in short order.

This report examines a scenario in which the United States is suddenly faced with a newly emerged intentional biological threat (biothreat) that could produce catastrophic public health consequences and threaten our economy, government, and social structure. This scenario was presented to 71 biodefense, medical, public health, life science, and homeland security thought leaders who were then asked what near-term and long-term policies and programs they would recommend in response to such an emerging crisis. Based on our analysis of their responses, this report condenses the best ideas into an organized set of proposals for leadership—in other words, this report is intended to provide a Jump Start for an effective response in a time of national crisis.

It is important to note that many of the recommendations made in this report, while focused on mitigating an impending biological threat, would be more effective if implemented before a biological crisis. We recognize the difficulties inherent in strengthening biopreparedness programs, but the greatest reduction of consequences can be achieved only through greater commitment of resources now. Waiting for a crisis will mean more lives lost and greater social and economic upheaval in the future.

Governance and Strategy

There was almost unanimous agreement among our interviewees that the threat posed in the Jump Start scenario would lead to demand for national leadership, substantially expanded biodefense capabilities, and political and financial support to enact those capabilities.

Address Deterrence and Prevention: Despite inherent difficulties, deterrence and prevention will be top priorities for action and will be by far the most cost-effective actions if they indeed prevent an attack and the resulting full-blown emergency response. Intelligence collection—albeit very difficult against all types of biothreats but, in particular, against nonstate biothreats—will be the single most important component of deterrence and prevention, followed closely by the threat of and/or use of military force if warranted.

Assess Risks and Vulnerabilities: The type of attacks described in the Jump Start scenario would require a new assessment of national risks and vulnerabilities. Existing planning assumptions regarding national risks from biological threats would need to be rapidly revised, as would assessment of national, state, and local vulnerabilities to biological threats.

Appoint a National Biodefense Leader and Task Force: The appointment of a dedicated biodefense leader—reporting directly to the President—and a task force of individuals with extensive executive branch and interagency experience to work exclusively on this problem would likely be critical to managing a
crisis of this magnitude. The Presidential Biodefense Task Force would be responsible for strategy, policy, and spending priorities and would work with cabinet secretaries and agency heads, who would provide substantive input and would be responsible for execution.

**Initiate Emergency Declarations and Actions:** Following a large-scale biological attack either in the United States or in a foreign country, a series of presidential declarations could be made, including a declaration of a national emergency under the National Emergencies Act, a declaration of a national disaster (Stafford Act), a declaration of a public health emergency by the Secretary of Health and Human Services, and, if applicable and needed, a Material Threat Determination (MTD) by the Secretary of Homeland Security. Additionally, the President should inform cabinet secretaries and congressional leaders of the intent, if needed, to use the Defense Production Act to facilitate a rapid response.

**Pre-Identify Risk Communications Messages and Approaches:** The Presidential Biodefense Task Force leadership team will need to communicate openly with the public about risks of infection, illness, and death; to explain how these risks can and will be managed; and to acknowledge uncertainties about the situation. Messages should not be overly reassuring or alarmist and should provide practical advice to the population about steps they can take to reduce their own risk.

**Public Health Response**

**Develop and Exercise Plans to Mitigate the Spread of Disease:** CDC should work with state and local stakeholders to develop plans for mitigating disease spread that are operationally feasible and consistent with the best available medical and scientific evidence. A concerted effort should be made to examine and test the sufficiency of existing national plans (including realistic exercises that “test to failure”) and plans to protect children and other vulnerable populations.

**Inventory and Expand on Existing Biosurveillance Systems:** The Office of the Assistant Secretary for Preparedness and Response (ASPR) in HHS, in conjunction with federal partners (CDC, DHS, DoD, etc), should conduct an inventory of existing surveillance systems and data streams and an analysis of where additional surveillance and information would be needed for situational awareness.

**Rapidly Strengthen the Public Health Emergency Workforce:** For public health agencies to respond to a Jump Start–like event, they would need to substantially increase staffing levels. In many places, this would require health departments to recruit and retain personnel to replace those lost to earlier layoffs and retirements. CDC should expand the number of Epidemic Intelligence Service (EIS) officers and increase the number of placements at state and local health departments.

**Medical Countermeasures**

**Engage with Industry Early On:** In the aftermath of a serious biological attack in the United States or elsewhere, there will be increased private-sector interest in developing medical countermeasures for the US government. Assuming that there is a declaration of a national emergency, public health emergency, or implementation of the Defense Production Act and use of National Security Exemptions to the Federal Acquisition Regulations, coordination between the federal government and the private sector will be
simplified. Under these conditions, resources for MCM R&D would be increased, the contracting process expedited, and industry potentially even compelled into action.

**Expand Resources for BARDA:** In the aftermath of a bioattack, the government organization responsible for the advanced development of medicines and vaccines for high-priority biological threats—the Biomedical Advanced Research and Development Authority (BARDA)—should be expanded and resourced appropriately, instead of creating a new, unproven model to provide MCMs for the US government.

**Develop a Concept of Operations for Using MCMs:** As new MCMs are developed, or existing products are manufactured on a large scale, it will be important to rapidly develop a clear concept of operations for how these new products are to be used. Given that medical countermeasures, even if produced on a large scale, will become available only over time, the concept of operations should reflect the fact that access to MCMs will need to be prioritized, with some groups receiving access earlier than others.

**Expand Diagnostic Laboratory Capacity:** Given the importance of laboratory analysis to infectious disease diagnostics, both state and federal public health laboratories, as well as clinical laboratories, would need funding to expand their capacity to deliver meaningful, timely information to decision makers and practitioners. Also, as the results of laboratory testing will inform the situational awareness and response strategies of policymakers and public health authorities, resources should be made available to complete the implementation of electronic laboratory reporting.

**Expedite Development of Point-of-Care Diagnostic Technology:** The use of point-of-care tests by healthcare providers could accelerate the identification and treatment of infected individuals. Important technical attributes of candidate assays that should be considered are high sensitivity and specificity for the pathogen of interest, rapid time to result, simplicity of use and interpretation, and cost. Once the assays have been developed and produced, the CDC should formulate and disseminate standard operating procedures to guide their use.

**Focus on Regulatory Review and Approval:** In the event of a major biological attack here in the United States, there would undoubtedly be public pressure to use unapproved countermeasures in an attempt to prevent or treat illness. The US government will need to balance a need for MCMs in such a scenario against the need to protect the public from harm that could come from releasing an MCM prematurely.

**Healthcare System Response**

**Create a National Health Response Concept of Operations:** A health system–specific concept of operations should be established that sets forth the roles, responsibilities, and expected actions in a catastrophic health event for each type of entity in the healthcare system (eg, hospitals, public health agencies, EMS, coalitions).

**Improve, Expand, and Connect Healthcare Emergency Preparedness and Response Coalitions:** Healthcare coalitions are now the backbone of US healthcare preparedness strategy. Coalitions could be strengthened by requiring federal medical facilities (military and VA) to be active participants in local healthcare coalitions and by increasing Hospital Preparedness Program (HPP) funding to support coalitions.
Improve Mass Casualty Transportation Capabilities: The existing National Ambulance Contract (administered by FEMA) should be expanded and made more capable with higher levels of medical care available and a more rapid deployment time. In conjunction, crisis standards of care plans for patient transportation should be developed that include use of nontraditional vehicles. Patient tracking systems should also be enhanced and expanded.

Enable US Acceptance of Foreign Assistance: HHS, the State Department, and FEMA should work together to find ways to overcome current obstacles to receiving international medical assistance.

Decontamination and Remediation

Prioritize Decontamination and Remediation: A national strategy, policy, and priorities for decontamination and remediation would need to be rapidly developed, including an implementation plan to aid in coordinating the large stakeholder group and the actions needed for remediation and reoccupation of a major city.

Address “How Clean Is Safe?”: A set of options for decontamination standards will need to be produced based on existing science, availability of medical countermeasures, and other public health, political, ethical, social, and fiscal considerations.

Prepare Laboratories to Test Environmental Samples: Environmental Response Laboratory Network facilities are equipped with the means and knowledge to process environmental samples from a biological attack. This network should be expanded and provided with guidance, reagents, and equipment to process biological samples for the purposes of environmental testing.

Establish Vaccination Policy: Currently, there is no policy on post-attack vaccination for a wide-area biological attack on a US city. Because it will be impossible to remediate to a level of zero contamination, and given that there will be residual risk to the public, if a safe, efficacious vaccine were to be available, strategic decisions regarding the use of that product would be necessary.

Environmental Detection

Expedite and Expand BioWatch Collection and Processing: In the immediate aftermath of a Jump Start–like scenario, enhancement of existing biodetection systems would be a logical first step, even with the uncertainties regarding the BioWatch system.

Evaluate Additional Detection Technologies for Use: Detection technologies should be evaluated that might provide complementary environmental detection capabilities either in the field or in the lab.
Conclusion

A large-scale biological attack, or campaign of attacks, against one or more US cities could lead to catastrophe, both in terms of lives lost and in economic and societal disruption. However, it is within the power of the US government to mitigate the consequences of a biological crisis through effective leadership, policy, research, and emergency response. The recommendations contained in this report reflect the best judgment of biodefense experts about what actions can and should be taken to reduce the impact of a national biological incident. If the recommendations in this report are fully implemented, the effects of a biological attack on this country could be significantly reduced.
Introduction

This report examines a scenario in which the United States is suddenly faced with a newly emerged intentional biological-threat (biothreat), one capable of producing catastrophic consequences. This scenario was presented to 71 biodefense, medical, public health, life science, and homeland security thought leaders who were then asked what near-term and long-term policies and programs they would recommend in response to the emerging crisis. Based on our analysis of their responses, this report condenses the best ideas into an organized set of proposals for leadership—in other words, the report is intended to provide a Jump Start for an effective response in a time of national crisis.

In an unconstrained resource environment, many of the recommendations contained in this report would logically be implemented prior to a biocrisis. In fact, the greatest reduction of consequences would be achieved through commitment of necessary resources now, and in no way should this report be seen as justification for a “just-in-time” biodefense system. Waiting for a crisis will mean greater consequences, more lives lost, and greater social and economic upheaval in the future.

However, we recognize that in today’s fiscal and political environments, with the wide variety of national security threats facing the United States, full implementation of these recommendations now is not likely. Therefore, this report focuses on providing recommended actions that should be taken in the setting of a major biocrisis in the United States or elsewhere in the world, when political and funding constraints would be diminished or gone. In that setting, the recommendations in this report should be fully embraced.

Naturally occurring infectious disease outbreaks are a global concern—as evidenced by the experiences with Ebola, MERS, and Chikungunya in recent months. A thinking enemy armed with equally dangerous pathogens, or with pathogens that are multidrug-resistant or engineered to be more lethal, could produce catastrophic public health consequences and potentially threaten our economy, our government, and our social structure.

During the Cold War, only major state powers had the capability to produce such bioweapons, properly classified as weapons of mass destruction (WMD). Today, advances in biotechnology, combined with the ubiquity of pathogens in nature, provide even less developed states, and some non-state actors, with the capability to conduct bioattacks ranging in sophistication from small events to a scale that could be classified as WMD.

Prevention and deterrence are the preferred strategies against the threat of weapons of mass destruction, and have been and will continue to be most effective against the nuclear threat. However,
the democratization of the capabilities to develop, produce, and deliver bioweapons—not appreciably different from the technologies widely used in the pharmaceutical and agricultural industries and in routine, even rudimentary science—make prevention approaches far more daunting than they are in the nuclear realm. Deterrence of biological attacks is challenging because of the scientific limits related to identifying the origins of a biological attack (microbial forensics). In addition, traditional concepts of deterrence (eg, the threat of retaliation against an aggressor’s homeland) do not readily apply to non-state actors. In other kinds of deterrence efforts (eg, drug trafficking, speeding, conventional warfare, etc), we presume some failures and prepare for them. We should do the same for biological threats.

Today, therefore, national priorities for defending against bioterrorism, particularly from non-state actors, must include the robust capacity to respond after an attack to save lives, care for the sick, and mitigate economic, social, and political disruptions. Strong preparedness will limit the impact of an attack and may even serve as a deterrent—where the aggressor may not choose to attack a nation that can effectively respond. An effective response capability is the central component of current biodefense strategy.¹

While much work and considerable resources have been expended on biopreparedness in the US, most efforts have focused on preparing for single-attack scenarios. Less work has been done on the preparation for multiple-attack scenarios or, to use a military term, a “campaign” that could continue for months or even years. These scenarios are often placed in the “too hard box” or are dismissed because they are “very unlikely.”

An extended campaign, made possible by the “reload effect,”” could have enormous public health, economic, social, and political impact. The reload effect has concerning aspects: (1) for any actor who can produce enough weaponized agent to attack a major city, the required technology and cost of producing enough material to attack additional cities will be minimal; and (2) a successful attack could motivate additional non-state actors, or even nation-states, to develop and use this type of asymmetric weapon.¹

Thus, an initial campaign of large-scale, sophisticated biological attacks would most certainly produce major changes in the national and international security equation.²

For this report, we posited a potential bioweapons scenario and asked a range of senior leaders in the biosecurity community to recommend changes that would need to occur to address the serious threats and challenges arising from an impending bioattack.

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² The “reload effect” is enabled by the inherent delay in detection and the difficulty of interdiction of a bioattack, and by the potential for large-scale production and ease of transport of biological agents that could be used in multiple locations to similar effect.

³ For this study, a large-scale, sophisticated bioterror attack is defined as an aerosol release of pathogens producing casualties (serious illness and/or death) in excess of 10,000 in each incident.
In this scenario, a bioattack occurs in the context of the current levels of US biopreparedness. We assume that the US will receive both strategic and tactical warning by way of a large-scale, sophisticated bioattack in another country—this is not a “bolt-out-of-the-blue” scenario. While there is certainly no guarantee the US would receive such a warning, this scenario was selected to demonstrate what could be accomplished if biodefense suddenly received the priority of the Manhattan Project or the Apollo program.

We also assume that in the days and weeks following a large-scale, sophisticated biological attack in another country (or in the US), the American people are likely to give the President and Congress broad support for taking extraordinary action—both political and fiscal capital that could ensure swift enactment of policies and programs to protect the country. This report provides an assessment, informed by the views of a spectrum of leaders in relevant fields, of policies and programs that would be most important in the aftermath of such an event. The interviews had a particular focus on governance, science and technology, and operational processes in building resilience against subsequent biological attacks.

Some examples of discussion questions are:

- What rapid improvements in governance (organizational structures, legal/regulatory issues, federal/state/local cooperation, etc) would be possible, assuming the President and congressional leaders had unprecedented political capital to make major changes in preparedness and response capabilities?

- What new scientific and technological advancements would be possible in 6 months, a year, or longer if the President declared them a top priority for national security?

- What new operational procedures could be initiated to provide major improvements in disease surveillance, situational awareness, rapid distribution and dispensing of medical countermeasures, and expanded capabilities for medical treatment?

Conducting this kind of analysis prior to an attack allows strategic planning over a period of months—something not possible in the midst of a national emergency. This report provides a recipe for response in advance so that it will be on hand in time of emergency.

While this Jump Start scenario focused on deliberate threats, many of the recommendations in this report also apply to severe naturally occurring epidemics.

* “Bolt-out-of-the-blue” is a term commonly used in the 1960s and 1970s to describe a surprise nuclear attack on the US by the Soviet Union. Most national security strategists generally assumed a scenario in which tensions built over time (e.g., Berlin crisis, Cuban missile crisis, Six Day War in the Middle East) as opposed to the scenario of a surprise attack while US forces were in DEFCON 5—the lowest level of preparedness. Unfortunately, bioweapon development programs can, and have, happened without detection by the intelligence community (e.g., aum Shinrikyo, South Africa, Iraq in early 1990s, al Qaeda, and, for the most part, a massive program in the Soviet Union during the 1970s). One criticism of this study could be the fact that the US will not likely have advanced warning of the Jump Start-like scenario, but this conceit was considered necessary for a methodology that would allow the examination of the time frames required for various initiatives to improve biodefense capabilities during a crisis.
Important Note

This report does not attempt to evaluate current biodefense efforts, and we recognize that some capabilities that may be envisioned and seen as valuable through the lens of this future scenario could be considered too costly or politically infeasible in the current environment.

It is important to emphasize that our preparedness efforts, for the most part, cannot be “just-in-time.” While a range of important changes would be made after a serious bioattack, there are many critical elements of biopreparedness and response capabilities that require long lead times—on the order of years. For certain problems, the timeline for solutions cannot be significantly shortened, no matter how much money is urgently spent. This is true for several recommendations in this report—in particular, the development of certain medical countermeasures (ie, vaccines, therapeutics, and diagnostics).

The country needs to make these kinds of critical, long-lead investments prior to a major bio-event. This report identifies those long lead-time investments while also showing what would be possible and urgent in the aftermath of a bioattack. Thus, the report is intended to be of high value now for long-range planning, as well as to be used to get an immediate jump start after an attack to prevent a disastrous situation from becoming a larger catastrophe.
Methodology

The UPMC Center for Health Security (the Center) staff reviewed the literature relevant to issues analyzed in the report. It assembled a team of Senior Advisors (see Appendix A) to assist with the development of the Jump Start scenario and the interview guide and to provide guidance and expert review of the final report.

**Relevant Literature Reviewed:** An extensive review of the published literature and policy and program documentation was conducted. Particular emphasis was placed on review of literature related to the different areas of focus in the study. The literature referenced in the report includes many of the seminal documents representing the US biodefense enterprise.

**Subject Matter Expert (SME) Interviews:** The staff conducted 71 semistructured telephone and in-person interviews with biodefense, medical, public health, life science, and homeland security thought leaders and experts (see Appendix B). The interview guide (see Appendix C) enabled an open-ended conversation. The guide was not followed exclusively, and the interviews progressed in additional directions where valuable. Interviewees were identified first through professional connections in the biodefense community and from the literature review. Interviewees were further identified via a snowball sampling methodology in which interviewees recommended other experts to participate in the study.

Interviewees included 31 individuals who were currently serving or had previously served at the Senior Executive Service level (SES) (or equivalent), in a wide range of federal government organizations, including: the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research and Development Authority (BARDA), the National Institute of Allergy and Infectious Diseases (NIAID), the Department of Homeland Security (DHS), the Central Intelligence Agency (CIA), the Joint Program Office for Chemical and Biological Defense (in DoD), the National Security Council (NSC) and the Homeland Security Council (HSC) at the White House, and the Environmental Protection Agency (EPA). Additional interviewees had extensive experience at the Red Cross, the National Defense University (NDU), the World Health Organization (WHO), on committees in the Senate and House of Representatives, in state and local public health offices, and in the biotech and pharmaceutical industries. The professional training credentials of the interviewees included 18 MDs, 3 DVMs, 32 PhDs in life sciences, 5 JDs, and 9 MPHs.

The interviews were scheduled for 60 minutes, but some lasted for more than 2 hours, and during a 9-month period, several individuals were interviewed more than once when more time was needed for interviewees to provide full responses. Prior to the interviews, interviewees were provided with a scenario developed by the Center with the assistance of Jump Start Senior Advisors.

The goal of the interviews was to create an environment to facilitate lightly structured brainstorming, while avoiding leading questions. There was one exception to this goal. Based on recommendations from the Senior Advisors, all interviewees were asked: “Is the current organizational structure of the federal government best suited for an effective, efficient response to the Jump Start scenario?”

The Senior Advisors participated in the creation of this report by reviewing drafts and providing comments. However, the authors are solely responsible for the analysis of the interviews and the recommendations in this report.
Jump Start Fictional Scenario Provided as a Read-Ahead

Large-scale bioattacks have occurred in Russia. Few details about the attacks have been made available, but officials have predicted that the casualties (those either sickened or killed) will exceed 10,000.

At least 2 different agents appear to have been used: anthrax (lab confirmed) and another that appears to be a contagious virus. The anthrax was reportedly released in several subway stations in central Moscow and in Red Square. Samples of the dry powdered anthrax agent have been obtained by Russian officials but not shared with other countries. Reports indicate that anthrax patients are showing significant resistance to several antibiotics. Elsewhere, officials in St. Petersburg are reporting hundreds of patients with hemorrhagic fever–like symptoms in multiple hospitals.

While remaining calm and measured in their public responses, the President and senior congressional leaders have privately expressed grave concerns that the attacks in Russia may be the beginning of a new era in warfare and terrorism. They understand that sophisticated, large-scale biological attacks could present a threat to national survival.

In addition to a team assembled to coordinate the immediate response to the ongoing international crisis, the President has asked a separate team to identify long-range strategic issues and priorities to improve America’s capability for bioterrorism. Interviewees in this study were asked to respond as if they were a member of the latter team.^

The President has asked for recommendations that could be implemented within the next 6 months, a year, or longer that would address priorities in the following categories:

- Governance (leadership and organizational structure, legal/regulatory issues, civil-military relations, federalism, etc)
- Science and Technology (detection and diagnosis, MCM development and production, cleanup)
- Operations Procedures (situational awareness, dispensing of MCMs, expanded capabilities for medical treatment)

Interviewees were asked to not limit their recommendations to the political, fiscal, societal, and public health realities of today. What could really be accomplished in a national crisis if biodefense had the priority of the Manhattan Project?

^ The main objective for the Jump Start study was to solely focus on issues with a time horizon of 6 months or longer. However, virtually all interviewees discussed many near-term issues that would require immediate attention. Therefore, in the Findings and Recommendations section of this report, we addressed issues for the first 6 months, 1 year, or longer.
FINDINGS AND RECOMMENDATIONS
Based on post-9/11 presidential directives; national, state, and local biodefense exercises; various biodefense response plans; and the National Planning Scenarios (for anthrax, plague, and influenza), the US strategy for biodefense has primarily focused resources on preparation and response capabilities that would limit the number of casualties and, to a lesser extent, prevention.

One could argue that this strategy has been appropriate for the threat environment of the past decade. However, there was almost unanimous agreement among our interviewees that the threat posed in the Jump Start scenario—bioattacks that could produce catastrophic public health consequences and threaten our economy, our government, and social structure—would lead to demand for national leadership, substantially expanded national biodefense capabilities, and political and financial support to enact those capabilities.

This effort would require a coordinated and comprehensive national strategy for biodefense, informed by a science-based understanding of the threat, and full consideration of the long-term costs and benefits of alternative courses of actions.

Given the level of national security threat posed in the Jump Start scenario, the vast majority of interviewees (and the authors of this report) concluded that previous and current biodefense leadership models and organizational structures would not be sufficient to ensure the most effective national response. (Today there are more than 4 dozen senior-level, executive branch leaders with major responsibilities for biopreparedness and bioresponse (see Appendix D for a list of presidentially appointed, Senate-confirmed individuals with major responsibilities for biodefense).

The following are important issues of governance and strategy for consideration in response to a newly emerged high-threat environment such as the Jump Start scenario.

**Address Deterrence and Prevention**

A dramatic increase in the threat of sophisticated, large-scale bioattacks would be a national security threat of the highest order that would require extraordinary national and international actions. Despite inherent difficulties (vide supra), deterrence and prevention will be the top priorities and will comprise by far the most cost-effective actions if they indeed prevent an attack and the resulting full-blown emergency response. Intelligence collection—albeit very difficult against all types of biothreats but, in particular, against non-state biothreats—will be the single most important component of deterrence and prevention, closely followed by the threat of and/or use of military force.

Intelligence collection against this newly emerged threat (Jump Start scenario) should be maximized globally—particularly working in close cooperation with the Russians and with allies (eg, NATO). Additionally, senior national security leaders would need to rethink the prioritization of deterrence and prevention, including the types of actions—ranging from international law enforcement efforts to military strikes if warranted—that may be considered infeasible in the current threat environment, but realistic in a scenario that threatens such enormous consequences.

**Initiate Crisis Response**

If deterrence and prevention fail, the recovery of the nation from a major bioattack, or campaign of attacks, would depend on the ability to maintain—or in more severe conditions, restore—basic government functions and economic viability, limit casualties, and avoid a situation that could rip the social fabric of the nation. A key element for success during response activities will be “staying ahead of the emergency”—in other words, being more proactive than reactive. This will require 5 key elements:

- Timely, accurate assessments of newly emerged risks and vulnerabilities;
- A national leader with the authority, responsibility, and accountability to ensure the most effective use of national assets;
- A streamlined, unified biodefense task force to lead all federal government efforts, coordinate state and local government activities, and provide clear guidance to biodefense assets in the private sector;
- Legal declarations that provide senior leaders with exceptional authorities for emergency response—before the event, if possible; and
- A coordinated national communications program to inform, educate, and gain the confidence and support of the American public.

**Assess Risks and Vulnerabilities**

The type of attacks described in the Jump Start scenario would require a new assessment of national risks and vulnerabilities. Existing planning assumptions regarding national risks from biological threats would need to be rapidly revised, as would national assessments regarding national, state, and local vulnerabilities to biological threats. This new risk and vulnerability assessment would require input from the intelligence community, the Department of Homeland Security, the State Department, the Department of Health and Human Services, the Federal Bureau of Investigation (FBI), the Department of Defense (DoD), the EPA, and other appropriate departments and agencies. It would need to be structured in a way that is useful for senior political leaders to make decisions and take action. This would require continued refinement as new information became available.

**Appoint a National Biodefense Leader**

In consultation with congressional leaders, the President should create a new position in the Executive Office of the President: an Assistant to the President for Biodefense. This individual would have the rank
equivalent to the National Security Advisor, the Homeland Security Advisor, and the Domestic Policy Advisor and would report directly to the President. The President would need to make it clear to all cabinet secretaries and agency heads in the executive branch that this individual speaks for the President, and interagency turf protection and bureaucratic stonewalling would not be acceptable or in the best interest of the American people during this period of national crisis. The appointment of a dedicated leader, leadership team, and organization to work exclusively on this problem would in all likelihood be needed to manage a potential crisis of this magnitude, given the need for the rest of the White House staff and structure to continue to manage all the other existing demands and requirements of national government.

This leader would need to have extensive executive-level leadership experience. A former governor or cabinet secretary would be an ideal candidate. Alternatively, a senior leader at the White House or an agency head could serve in this role, depending on his or her skills, knowledge, and working relationships across government. Regardless of background, the Assistant to the President for Biodefense will need to avoid party politics and work across the aisle to ensure that the best policies and science are applied to the problem.

Additionally, the President should appoint a Deputy Assistant to the President for Biodefense—an individual with strong scientific and medical/public health credentials, such as an individual with senior leadership experience at HHS. The Deputy Assistant to the President for Biodefense would chair all deputies’ committee meetings addressing biodefense issues. This leadership dyad, in some respects reminiscent of the Manhattan Project (ie, Leslie Groves and Robert Oppenheimer), would be needed to handle the complex challenges of this new threat environment.

Virtually all interviewees recommended the creation of a new executive position to lead national biodefense efforts. Additionally, the majority of interviewees stated that a streamlined biodefense organizational structure would also be required to effectively manage the diverse components involved in a national response to this new threat.

### Assemble a Presidential Biodefense Task Force

In consultation with congressional leaders, the President should create, by executive order, a Presidential Biodefense Task Force to deal with the newly identified biological threats to the country. This task force would exist in the Executive Office of the President. The Presidential Biodefense Task Force leadership dyad would then select other highly experienced individuals to fill the leadership positions in the task force. Some of these positions could be filled with individuals who currently work, or have recently worked, in the Executive Office of the President (National Security Council staff, Office of Management and Budget, Council of Economic Advisors, Office of Science and Technology Policy), in departments and agencies in the executive branch, and other White House staff.

* The structure and functions of this task force were designed to align with the Incident Command System/National Incident Management System (ICS/NIMS) currently used by federal, state, tribal, and local governments.
There will be no time for on-the-job training. All key personnel assigned to the Presidential Biodefense Task Force must have extensive experience working in the interagency environment, and this would need to be their full-time job.

In the descriptions to follow, we have suggested experience requirements for various key leadership positions. These are notional, and only meant to describe the type of professional and leadership experience best suited for these challenging positions. The diagram below is also notional and meant to serve as an example of a unified organizational structure to lead a national biodefense enterprise in time of crisis.

The Presidential Biodefense Task Force would be responsible for strategy, policy, and spending priorities. The cabinet secretaries and agency heads would be responsible both for substantive input and for execution. This would not be a permanent organization. At some point in the future—following resolution of the biodefense crisis—it would be integrated back into a more traditional NSC/NSS policymaking structure.

Key leadership positions and advisory groups include the following:

The **Senior Director for Biodefense Plans and Operations** would have responsibility for developing strategies, policies, and spending priorities and for coordinating all biodefense plans across the federal government. In addition, this individual would coordinate information flow and situational awareness through a fusion center that collects and synthesizes intelligence and open-source information. This position could be filled by a former deputy director of the CDC, a director of CDC’s Office of Public Health Preparedness and Response (OPHPR), a deputy FEMA director, a Red Cross director of operations, or someone of equivalent experience.

The **Senior Director for Biological Science and Technology** would have responsibility for developing strategies, policies, and spending priorities and coordinating all biodefense research and development across the federal government. This position should be filled by someone with extensive senior leadership at BARDA, the National Institutes for Health (NIH), the FDA, or the DoD.

The Senior Directors for Biodefense Plans and Operations and Biological Science and Technology would chair all interagency policy coordinating committees with responsibilities for biodefense.

The **Senior Director for Office of Management and Budget (OMB) and Congressional Liaison** would work directly with the OMB director and relevant congressional committee chairs to ensure rapid decisions on appropriations and authorizations. This position would require a leader with extensive OMB experience, such as a former deputy director of OMB, a program associate director for health programs, or a senior member of the White House Office of Legislative Affairs.

The **Biodefense Science Board** would provide a national brain trust of expertise on a broad range of issues, including medicine, public health, life sciences, the pharmaceutical industry, biotech, intelligence, and homeland security. Panel members would be recruited from both inside and outside government (eg, industry and academia) for this full-time (paid) yet temporary duty. This group would identify critical
issues, ranging from gaps in capabilities to game-changing technologies and operational procedures, and respond to assignments from the Presidential Biodefense Task Force leadership team. One model for this organization could be to create a federally funded research and development center (FFRDC) or make use of an existing FFRDC to help create the structure required. This expert committee would not engage in laboratory research, but would provide analysis and recommendations that could be assigned to government or private sector organizations.

Many of these individuals could be recruited from existing advisory organizations, such as the President’s Council of Advisors on Science and Technology (PCAST), the National Science Advisory Board for Biosecurity (NSABB), the Defense Science Board, the DNI Biological Sciences Experts Group, and DoD’s science and technology advisory group, JASON, as well as scientists from the National Academy of Sciences with relevant expertise. Since this group would be providing expert advice on operational procedures, membership should also include representatives with extensive operational experience in state and local public health and disaster response.

The Bioethics Advisory Panel would be composed of leaders from the medical, public health, scientific, and academic communities as well as religious thought leaders to provide advice and counsel directly to the Assistant to the President for Biodefense. Understanding these challenges, and effectively communicating the rationale for certain decisions (e.g., crisis standards of care, rationing of critical resources, privacy issues, etc), will be an important element of a successful response.

The Liaison to State and Local Leaders would be responsible for ensuring effective communications with state and local governments. The failure to provide effective 2-way communications between federal and state/local governments (including public health agencies and emergency management offices) in past disasters was one of the most common problems identified by our interviewees. A former lieutenant governor or mayor would be well suited for this position.

The General Counsel would provide legal counsel to the Assistant to the President for Biodefense and serve as a liaison with the White House counsel and the general counsels from key departments and agencies. The National Communications Task Force would develop a national program to inform, educate, and gain the confidence and support of the American public (details on duties and responsibilities discussed at the end of this section).

* The Presidential Commission for the Study of Bioethical Issues could be used for this critical advisory group, but it is currently scheduled to end in September 2015.
Notional White House Structure in Response to a Biocrisis

President

Assistant to the President for Biosecurity

Liaison to State and Local Governments

General Counsel

Deputy Assistant to the President for Biosecurity

Bioscience & Technology

Biodefense Science Board

National Communications Task Force

Omb & Congressional Liaison

Bioethics Advisory Panel

Initiate Emergency Declarations and Actions

**National Emergency**—Following a large-scale biological attack either in the US or in a foreign country, as described in the Jump Start scenario, a series of presidential declarations could be made, including declaration of a national emergency under the National Emergencies Act, declaration of a national disaster (Stafford Act), a declaration of a public health emergency by the Secretary of Health and Human Services, and, if applicable and needed, a Material Threat Determination (MTD) by the Secretary of Homeland Security.

The declaration of a national emergency has precedent in recent history. President Bush declared a national emergency 3 days after 9/11. President Obama declared a national emergency in October 24, 2009, during the H1N1 pandemic and a continuation of the Bush 9/11 declaration on September 9, 2011.4

Declaring a national emergency provides the President with a broad range of legal authorities, including personnel actions for military and civilian federal employees and access to emergency funds already...
appropriated by Congress. It would provide a clear message to all federal, state, and local government employees, nongovernmental organizations, business leaders, and the American public that this is a national security issue in which the federal government, and, in particular, the President, has primary responsibility.

**Stafford Act**—A presidential declaration of the Stafford Act enables access to the Disaster Relief Fund—several billion dollars immediately available to state and local governments. In most cases, a Stafford Act declaration is not made until it is requested by a governor. However, this is not required if the President determines “any occasion or instance” when federal aid is needed by state and local governments to save lives and property or to address the threat of a catastrophe.

Declaring a national emergency, and stating that the threat of bioattacks constitutes a threat to national security, would allow a Stafford Act declaration solely on presidential authority. Additionally, a Stafford Act declaration allows the Secretary of Health and Human Services (under Section 319 of the Public Health Service Act) to declare a public health emergency.

**Public Health Emergency**—Powers granted to the HHS Secretary during a public health emergency would play a key role in staying ahead of the emergency. It authorizes the HHS Secretary to take appropriate emergency actions including, but not limited to:

- Letting grants and contracts for investigation into causes, treatments, and preventive measures that can be taken;
- Using “no-year” funds from the Public Health Emergency Fund;
- Moving or appointing federal personnel to temporary positions for response to the emergency;
- Authorizing state or tribal governments to assign state and local public health department personnel (funded under federal programs) to temporary positions for the purpose emergency response;
- Adjusting reimbursement for certain Medicare Part B drugs, needed for response to the emergency, in order to make those drugs available and affordable;
- Relaxing grant requirements and timelines while emergency response is ongoing;
- Relaxing some Medicare, Medicaid, Children’s Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPPA) requirements.

**Material Threat Determination**—In a Jump Start–like scenario, the Secretary of Homeland Security should “determine a material threat against the United States population sufficient to affect national security.” This material threat determination would allow the Secretary of HHS to authorize emergency use of certain medical countermeasures (ie, vaccines, therapeutics, and diagnostics). A recent example of this occurred in August 2014 in response to the Ebola outbreak.

* Presidential declarations of the Stafford Act were made after the 9/11 attacks and after the bombing of the Murrah Federal Building in Oklahoma City in 1995.
Defense Production Act (PL 81-774)—The President should inform cabinet secretaries and congressional leaders of the intent to use the Defense Production Act to facilitate a rapid response. This law was passed during the Korean War and has been periodically reauthorized and amended since 1950. In 2012, Executive Order (EO) 12919 provided additional guidance for implementation. If the President creates a new position of Assistant to the President for Biosecurity during a crisis, a few amendments to EO 12919 would be appropriate to ensure continuity of leadership responsibilities. The Act provides extraordinary authority to the President: to sign contracts and allocate materials, services, and facilities deemed necessary for national security. It also authorizes the President to control the civilian economy to ensure the best use of scarce materials, requisition property, force industry to expand production, and impose wage and price controls during a national crisis.

National Security Exemptions to the Federal Acquisition Regulations—The President should direct all cabinet officers and agency heads to use these exemptions whenever possible to avoid contracting delays. The Presidential Biodefense Task Force should immediately issue policy guidance on the use of these exemptions.

These proactive emergency declarations and actions, and perhaps others that Congress may choose to authorize, will be the primary means to get out in front of the crisis in terms of authorizations for actions, funding, overcoming the challenges of coordinating federal/state/local government actions, and engaging the American public.

Pre-Identify Risk Communication Messages and Approaches

Risk communication will be one of the most critical elements of the US approach to response in a Jump Start–like scenario. During the response to cases of Ebola in the US in 2014, some of the risk communication messages were initially overly reassuring, not taking into account the uncertainty in scientific knowledge about Ebola virus, and inadvertently simplifying the risks, possibly in an attempt to avoid causing public alarm. Messages that understated the problem, such as “there is no risk to the public,” were detrimental to communications efforts when transmission of Ebola did occur, even if that transmission was in the healthcare workforce and not in the public at large. This resulted in decreased public trust and confidence and sowed doubt about the government’s ability to protect the public. Subsequently, messaging moved in the other direction, suggesting that response measures not supported by scientific evidence be undertaken “out of an abundance of caution.” This kind of messaging also resulted in public confusion and loss of trust in the response, and led to the uneven application of restrictive response measures, which had implications for civil liberties and local economies.

In an environment where there is imminent threat of illness and death, public risk perception and thresholds for acceptance of risk will likely change dramatically. The Presidential Biodefense Task Force leadership team will need to communicate openly with the public about risks of infection, illness, and death; to explain how these risks can and will be managed; and to acknowledge uncertainties about the situation. Messages

* Some responsibilities currently assigned to the Secretaries of Homeland Security and Defense might be transferred to the Assistant to the President for Biosecurity.
should not be overly reassuring or alarmist and should provide practical advice to the population about steps they can take to reduce their own risk. In addition, special attention should be paid to communication with public health, emergency management, and healthcare providers so that confusion is minimized in those communities.

Finally, messages surrounding complex topics, such as clinical guidance for infection control or information about experimental medical countermeasures, should be pretested with the public and with professional communities. Incorporating feedback about risk messages can help avoid missteps that would damage government’s credibility and ability to carry out an effective response.

**Engage Trusted Risk Communicators**

The National Communications Task Force will need to quickly identify individuals who can be trained to serve as communicators in a crisis and help to amplify important public health protective messages. As evidenced by the recent measles epidemic in the US and the global Ebola crisis, there are clinicians and other figures with large media platforms who promulgate views that are not supported by current medical evidence and who could substantially undermine the public health response to an epidemic. To counter these potentially harmful voices, the nation will need a force of camera-ready and social media–trained individuals who can speak to local press about the importance of adhering to public health recommendations. Preferably these individuals would be recognized experts (physicians, nurses, researchers, etc), both at the national and local levels, in public health and medicine who come from diverse backgrounds.

It will be important to recognize that the public receives their news from a variety of traditional and social media sources. The more that government officials can interact with this range of news platforms to disseminate their messages, the better the uptake will be. Additionally, it will be important for communications experts to monitor traditional and social media to understand where there is confusion, mistrust, and doubt, so that messaging can be adjusted to improve public and professional uptake of protective recommendations.
Public Health Response

Since 2001, the US has devoted considerable resources to bolstering the nation’s public health infrastructure to improve its ability to withstand a bioterrorist attack. Recognizing the foundational role that state and local health departments play in protecting US public health, the federal government has made support for state and local health departments a central priority in national plans for responding to public health emergencies. Through its Public Health Emergency Preparedness Cooperative Agreements, CDC has provided $10 billion in funding to states, major metropolitan areas, and territories in the past 15 years, to improve their readiness for a range of public health threats.

These investments have paid off. The nation now maintains a network of laboratories in every state dedicated to providing 24/7/365 access to testing and subject matter expertise for biothreats and other pathogens and agents. Health departments can now distribute important updates to healthcare facilities via a national Health Alert Network. States have developed and exercised plans to rapidly distribute antibiotics following an anthrax attack. The number of epidemiologists working in public health departments on emergency response doubled from 2001 from 2006.11

Although there has been meaningful progress in responding to small- to moderate-scale outbreaks, there remains troubling evidence that the US is not yet prepared to respond to a large-scale biological attack or other catastrophic health emergency.12 Most concerning is evidence that as federal investments in public health preparedness funding have faltered, the nation has been losing capacity in state and local health departments. The US’s ability to respond to health emergencies hinges on having highly skilled, experienced public health personnel who can rapidly detect a biological attack and help lead the response to mitigate its consequences. But steady declines in federal funding for public health preparedness and the economic downturn have led to significant reductions in the workforce and in preparedness programs in state public health agencies. From 2008 to 2011, state and local public health agencies lost more than 45,000 jobs. As a result, in 2012 nearly half of all local health departments reported having reduced or eliminated services, with immunizations and emergency preparedness services among the most frequently affected program areas.

There are other worrying indicators of lack of public health readiness. Although the nation now boasts a highly competent public health laboratory network, which has been a critical component in managing circumscribed national crises like the measles outbreak and US Ebola cases, a recent report found that the laboratories in this network do not have the capability to maintain a sustained surge in testing that would likely be needed during a biological attack.13

Following the emergency declarations described in the Governance and Strategy section of this report, the public health initiatives recommended below would significantly improve response capabilities in the aftermath of the Jump Start scenario.

Although the US has made considerable progress in improving its ability to respond to public health emergencies, it has not yet achieved readiness for large-scale crises like a major biological attack. Unpredictable and declining levels of federal funding have made it impossible for states to prepare for catastrophic scenarios beyond geographically limited public health emergencies.
Develop Plans to Mitigate the Spread of Disease

The US experience in the early days of the 2009 H1N1 pandemic and the appearance of Ebola cases in the US shed an important light on the inadequacies of existing plans for using non-pharmaceutical interventions (NPIs) to mitigate the spread of a contagious illness. In H1N1, inconsistent policies between cities and states about closing schools undermined public confidence in governments’ response to the crisis and created barriers for working parents, including healthcare personnel, who could not report to work. After the appearance of Ebola in the US, some states took unnecessary measures to quarantine uninfected individuals who had had contact with Ebola patients (such as clinicians returning from West Africa). In both of these cases, political pressures to demonstrate action led to the inappropriate use of non-pharmaceutical interventions that did little to alter the spread of contagion, exacerbated the social and economic consequences of the disease, and provided mixed messages to the public about risk.

To prevent similar problems from arising in the aftermath of a biological attack, where the political stakes are likely to be even higher, the CDC should work with state and local stakeholders to develop plans for mitigating disease spread that are operationally feasible and consistent with the best available medical and scientific evidence. At a minimum, these plans should determine under which circumstances, if ever, the following measures are appropriate for mitigating the spread of disease: quarantine and isolation, airport and other transportation closures, restrictions of mass gatherings, and school closures. This work would be intended to ensure that, during a crisis, states would be prepared to implement non-pharmaceutical interventions that could meaningfully protect public health while preserving individual liberties, minimizing social and economic consequences, and communicating clear and consistent messages about risk.

Exercise Response Plans to Failure

In a Jump Start–like scenario, the US government should immediately develop and commence a series of national and local functional and tabletop exercises aimed at testing national readiness to biological attacks. The scope of these exercises should include scenarios to test readiness to distribute vaccines and other medical countermeasures, as well as a response to a biological scenario in which countermeasures are not available or effective. Though the US has required regular exercises around these scenarios, political and other pressures often prevent these events from being a true test of the system. New and more challenging scenarios are needed to ensure that exercises are not just an opportunity to demonstrate success, but rather to examine the feasibility, effectiveness, and limits of existing response plans. Tabletop exercises should be developed to identify potential points of failure in presumed response plans to help refine or rewrite existing plans. Functional exercises should be conducted to test the response plan feasibility.

Protect Pediatric and Other Vulnerable Populations

The US maintains a Strategic National Stockpile (SNS) of medical countermeasures and personal protective equipment to address a range of major threats to the country. One serious challenge is that the contents of this stockpile do not adequately address the needs of portions of the US population, particularly children.
For example, recent surveys found that 40% of the medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) agents in the SNS have not been approved for pediatric use.\textsuperscript{14} In large part, progress toward development of pediatric-appropriate SNS countermeasures has been more limited because of funding and ethical questions about extending clinical trials to children in the absence of a CBRN threat. These barriers would need to be revisited in the aftermath of a major biological attack in the US or elsewhere in the world. In this setting, there should be a high priority placed on examining the sufficiency of existing national plans and contents of the SNS to protect children and other vulnerable populations.

**Provide Critical Electronic Health Record Data to Public Health Departments**

In the response to a biological attack, real-time exchange of patient-level data between clinical and public health communities would be critical for assessing the impact of the attack and for devising plans for responding. In an unfolding event, public health departments need to collect some detailed data about patients who are affected in order to understand key aspects of the outbreak. While there has been a concerted effort and significant funding allotted to developing electronic health records and to encouraging their adoption by medical providers, less attention and funding support have been allocated to making sure the information contained in electronic health records (EHRs) is available to public health departments during a crisis. While some public health departments may receive some electronic data from EHRs, such as immunization records and laboratory reports, few have the ability to access EHRs in real time and in a flexible, query-based way that is likely to provide the answers necessary to better understand an event as it unfolds. As an immediate priority, the HHS Office of the National Coordinator for Health Information Technology (ONC) should work with CDC and the Centers for Medicare and Medicaid Services (CMS), together with input from state and local public health stakeholders, to define and implement national data standards aimed at improving public health departments’ access to EHRs during public health emergencies. CDC should work with state and local stakeholders to determine how to best access and use essential public health data contained in EHRs in a manner that assures the security and confidentiality of patient information.

**Inventory and Expand on Existing Biosurveillance Systems**

In a Jump Start–like scenario, the sufficiency of existing biosurveillance systems to support decision making at the local, state, and national levels would need to be evaluated. In planning related to biosurveillance, there should be an inventory of decisions that would be needed throughout a response, and an analysis of where existing information systems provide sufficient information to support decision making and where they do not.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) in HHS, in conjunction with federal partners (CDC, DHS, DoD, etc) should work with states to define logistical and supply chain information needed in response to a biological attack. For example, previous analyses have found that while most public health surveillance systems focus on data related to the number of infected patients, they often lack data pertaining to availability of hospital beds, pharmaceuticals, personal protective equipment,
and other medical supplies that are necessary to make informed decisions about how best to respond to a biological attack. US agencies should work with states to define a minimum set of information that will be needed to manage a large-scale attack. The US government could bring those needs to the private sector and identify potential ways to collect that data and create data-sharing provisions (eg, confidentiality agreements, de-identification steps, etc) needed to share this information with response agencies.

Expand and Strengthen the Public Health Workforce

For public health agencies to respond to this kind of event, they will need a staff of professionals that is substantially larger than that in place today following years of cuts. In many places, this would require health departments to recruit and retain personnel to replace those lost to earlier layoffs and retirements. CDC should expand the class of Epidemic Intelligence Service (EIS) officers to increase the number of placements at state and local health departments. Additionally, well-trained public health experts could be encouraged to seek employment at health departments by appropriating funds to implement the public health workforce loan repayment-for-service program authorized by the 2006 Pandemic and All-Hazards Preparedness Act.
Medical Countermeasures

Medical countermeasures (MCMs)—drugs, vaccines, diagnostic tests, and other medical devices—are an important part of preparedness against a biological attack. Developing a robust MCM enterprise to provide countermeasures for biodefense and emerging infectious diseases has been challenging for a range of technical, organizational, administrative, and financial reasons. The development process is complex, and there are many risks. Testing to make sure a drug or vaccine works in humans in advance of an event is not possible for many of the biological threats, so establishing the efficacy of countermeasures usually requires studies in animal models—a development pathway that can be lengthy and uncertain.

In addition to the technical intricacies of MCM development, there are financial challenges to building an MCM enterprise. The only customer for most biodefense products is the US government, and so costs to develop, manufacture, and stockpile countermeasures have to be borne by government. As costs can run over a billion dollars for the development of a single countermeasure, the US government threat assessment process and the priorities for investment in MCMs that come out of that process are important. While there are now many countermeasures stockpiled, there are some threats for which we do not yet have MCM tools available. Given the range of potential threats, the development and stockpiling of countermeasures for all of them has been out of budgetary reach.

In spite of these challenges, a government-led system to produce and procure MCMs has been developed over time, with several government agencies having responsibility. At the top of the system is the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which was put into place in 2006. PHEMCE is led by the ASPR, and it includes 4 HHS agencies or offices: CDC, NIH, BARDA, and FDA. It also includes other non-HHS agencies that have responsibilities for MCM development: DHS, DoD, the Department of Veterans Affairs (VA), and the Department of Agriculture (USDA). While not every product has conformed to this model, the beginning stages of research into medical countermeasures in HHS are the responsibility of the NIH—specifically NIAID. BARDA is responsible for advanced research, development, and manufacturing of MCMs.

Until 2003, the DoD was responsible for most MCM development in the US government, but their “customer” is the warfighter, not the entire US population. Requirements for countermeasures are set by the Joint Requirements Office (JRO). The Chemical and Biological Defense Program (CBDP), which is responsible for turning those requirements into products, has several components: Research and discovery are performed by the Defense Threat Reduction Agency Joint Science and Technology Office (DTRA-JSTO) or sometimes by the Defense Advanced Research Projects Agency (DARPA). Advanced development of DTRA-JSTO products is undertaken by the Joint Program Executive Office—Chemical/Biological Defense (JPEO-CBD).

There is an agreement between HHS and DoD for an integrated portfolio of MCMs, established in 2010, and there is now a set of common definitions for HHS and DoD for technology readiness levels (TRLs) to facilitate communication about specific countermeasures.
The US government has also invested in capabilities to improve the manufacturing of countermeasures. On June 15, 2012, HHS awarded contracts to 3 Centers for Innovation in Advanced Development and Manufacturing based in Maryland, North Carolina, and Texas. The objective of these centers is to use public-private partnerships to coalesce expertise in development and manufacturing of MCMs from biotechnology companies, academic institutions, and large pharmaceutical companies. The concept of use for these facilities includes a plan for an emergency role. The products from these manufacturing sites, as well as from other traditional pharmaceutical manufacturing plants, could potentially be used under an Emergency Use Authorization (EUA). An EUA allows the Commissioner of the FDA to authorize the use of previously unlicensed or unapproved medical products, or unapproved uses of approved medical products, in an emergency to diagnose, treat, or prevent diseases caused by bioterrorism (or other CBRN) threat agents when certain criteria are met (eg, when there are no adequate, approved, or available alternative MCMs).

In a Jump Start–like scenario, medical countermeasures (eg, vaccines, drugs, and diagnostic tests) may need to be developed, tested, and distributed quickly. This effort will need to be coordinated and executed between the government and private industry. The following recommendations are aimed at streamlining and improving this process.

**Engage with Industry Early On**

In the aftermath of a serious biological attack in the US or elsewhere, there will be increased private-sector interest in developing medical countermeasures for the US government, as evidenced by the private sector role in the Ebola epidemic in West Africa of 2014-15. Assuming that there is a declaration of a national emergency, public health emergency, or implementation of the Defense Production Act and use of National Security Exemptions to the Federal Acquisition Regulations, coordination between the federal government and private sector will be simplified. Under these conditions, resources for MCM R&D will be increased, the contracting process expedited, and industry more engaged or potentially even compelled into action.

Establishing effective, strong, direct industry involvement, as well as access to pharmaceutical expertise in the US government, will be a critical element of developing needed MCMs in these conditions. If industry is reluctant to focus development and manufacturing efforts on the response, government should be prepared to discuss and quickly decide on alternatives, additional incentives, or other approaches to engaging industry.

**Expand Resources for BARDA**

The current MCM development process—largely the responsibility of BARDA in its role of promoting the advanced development of MCMs—has had successes since the creation of the PHEMCE process. However, BARDA has never had resources sufficient to support the advanced development of the medical countermeasures necessary to respond to all high-priority biological threats. With additional resources rapidly made available, and significant increases in highly skilled personnel rapidly brought into BARDA through a public health emergency declaration, the current system could be used successfully to lead and
coordinate the development and production of new MCMs. In the aftermath of a bioattack, leaders should expand BARDA instead of creating a new, unproven model to provide MCMs for the US government.

**Change Contracting in HHS for MCMs and Encourage Other Reforms**

The Assistant to the President for Biodefense should direct the Secretary of HHS to implement national security exemptions to the Federal Acquisition Regulations (FAR) for all actions in the MCM process. There will be a need for the greatest possible speed and efficiency in this crisis, particularly in contracting. The Federal Acquisition Regulations currently place an onerous administrative burden on the private sector, minimizing short-term risks to the government but increasing the risks of ultimately failing to produce a countermeasure. Other Transaction Authority would enable a more effective and flexible partnership between the government and the product developer, but it has not often been used in the MCM development system. In the event of a Jump Start–like scenario, Defense Production Act (DPA) provisions should be placed into BARDA contracts.

**Develop a Concept of Operations for Using MCMs**

As new products are developed, or existing products are manufactured on a large scale, it will be important for PHEMCE to rapidly develop a clear concept of operations (conops) for how these new products are to be used. Given that medical countermeasures, even if produced on a large scale, will become available only over time, the concept of operations should reflect the fact that access to MCMs will need to be prioritized, with some groups receiving access earlier than others. Robust data collection plans will need to be in place to ensure that new countermeasures that are developed and administered in the crisis are safe and effective. It will be critical to keep the public informed about this information as it becomes available.

**Invest in Technologies to Improve MCM Development and Regulatory Science**

A long-term goal should be to expand investment in the technologies that facilitate MCM development and manufacturing. These will not affect the MCM process in the short term but could potentially lower costs and increase effectiveness in the long term. Expanding the tech base for all elements of the MCM pipelines, from basic research through manufacturing advances, will mean increased funding for programs including those at NIH, the National Science Foundation (NSF), and DARPA.

While there are many aspects of MCM development, manufacturing, and administration that would be of great importance following an attack (eg, MCM delivery in a temperature-stable patch, distributed manufacturing, shortened development times benefiting from access to scientific databases, testing of discarded drug compounds, long shelf lives, etc), technology “silver bullets” should be thought of as long-term goals requiring careful development and steady funding over a period of years. Pathogen-specific research is likewise a multi-year process that may prove useful, as it did in developing medical

* Several interviewees discussed these national security exemptions to the FAR. Two interviewees stated that contracting issues resulted in no delays during the acquisition of 100 million doses of smallpox vaccine in 2003.
countermeasures for Ebola. MCMs are not likely to be immediately available in time to be useful during the initial response to a crisis. To be available in the medium to long term, they will require government resources to track, nurture, and safely shepherd development from early stages into actual, usable technologies and countermeasures.

**Determine Use Cases and Product Specifications for Diagnostics**

In the event that diagnostic technology solutions are not readily available for the threats at hand, the Presidential Biodefense Task Force should immediately convene a diagnostic technology working group, to include representatives from industry, academia, government (particularly BARDA, CDC, FDA, NIH, and DoD), and end users. The purpose of the group would be to agree on concepts of operations, use cases, and product specifications for any newly needed diagnostic technologies. This work should describe how, where, and by whom the existing or proposed diagnostic technologies are intended to be used. The working group should review relevant products and technologies that are either already commercially available or are in the R&D pipeline, and select the most appropriate platform or platforms to prioritize for rapid late-stage development and manufacturing.

**Expand Diagnostic Laboratory Capacity**

The initial indication that a biological attack has occurred will probably be the presentation, evaluation, and diagnosis of infected individuals. A definitive diagnosis is often achieved through identification of a pathogen or other evidence of infection (ie, antibodies) in clinical samples (eg, blood, sputum, cerebrospinal fluid, etc).

Today, the diagnostic process for most pathogens requires samples to be collected and transported to a hospital-based or independent clinical laboratory for analysis. Once there, laboratorians use a variety of techniques to identify the pathogen, including culture, microscopy, antigen-based tests, and nucleic acid-based tests. Given the centrality of laboratory analysis to infectious disease diagnostics, both state and federal public health laboratories, as well as clinical laboratories, would need the funding to expand their capacity to deliver meaningful, timely information to decision makers and practitioners. This surge capacity could be created internally by adding personnel and resources or by adopting technologies that automate common laboratory procedures. Alternatively, government could partner with large-scale private-sector clinical laboratories to provide additional diagnostic capacity.

The Laboratory Response Network (LRN) is a well-established public health laboratory network with national coverage, the ability to safely work with threat agents, access to sophisticated diagnostic technologies such as next-generation sequencing, and an experienced workforce. The LRN should be well resourced and potentially expanded during the crisis period. As the results of laboratory testing will inform the situational awareness and response strategies of policymakers and public health authorities, one priority action should be to increase the funding and technical support available to complete the implementation of electronic laboratory reporting.
Expedite Development of Point-of-Care Diagnostic Technologies

While laboratories are and will remain the backbone of the nation’s diagnostic capability for the foreseeable future, it is now technologically feasible to conduct some diagnostic tests at the bedside. In the near term, several foundational technologies could provide a point-of-care diagnostic capability, including lateral flow assays, microfluidics platforms, and single and multiplex molecular diagnostics. Operational advantages of point-of-care technologies include rapid time to result (within 30 minutes) and ease of use by clinical staff who lack extensive training in laboratory methods. The availability of an accurate and reliable point-of-care assay for the attack pathogen would facilitate the rapid identification of cases once an attack has been recognized. Further, such a test would speed discrimination of the truly infected from the “worried well” and could also inform decisions regarding the use of pharmaceutical and nonpharmaceutical interventions.

In order to speed assay development and validation, PHEMCE could enable developers’ access to the attack pathogen in various clinical samples. Once the assays have been developed and produced, the CDC should formulate and disseminate standard operating procedures to guide their use. Important technical attributes of candidate assays that should be considered are high sensitivity and specificity for the pathogen of interest, rapid time to result, simplicity of use and interpretation, and cost. The development of a diagnostic strategy should also take into account the attack pathogen’s characteristics (eg, transmissibility, timing of infectiousness, and dynamics of disease progression) and should provide meaningful information for public health or medical decision making.

The use of point-of-care tests by healthcare providers could expedite the identification and treatment of infected individuals. Potential use cases for point-of-care diagnostics include a relatively simple test intended for use during mass triage outside of a traditional clinical setting, and an assay meant for use in a clinical setting that has increased performance or functionality. Separately, an assay able to distinguish between a bacterial and nonbacterial (ie, viral) etiology would very useful for both the crisis period and for the routine provision of medical care.

In the longer term, the ubiquity of smartphones, wearable technologies, and cloud computing present opportunities to unify the performance, analysis, and result reporting of diagnostic tests for biosurveillance and medical applications, but will also require substantial investment and forethought. The merger of distributed diagnostics with information technologies could provide unprecedented levels of situational awareness and biosurveillance information.

Focus on Regulatory Review and Approval

It is likely in a Jump Start–like scenario that MCMs needed for the prevention, treatment, or diagnosis of infection will not have been licensed, approved, or cleared by the FDA. In this case, the FDA has mechanisms to enable access to unproven MCMs. For example, the FDA may issue an EUA to enable access to unapproved MCMs or MCMs not approved for the intended use. The criteria—required for a vaccine, drug, or devices, including diagnostic tests—for the FDA to issue an EUA include the following:

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1. **Emergency Use Authorization (EUA)**: The FDA may issue an EUA when there is no adequate and approved alternative to the product and the potential benefits outweigh the potential risks.
2. **EUA Criteria**:
   - **Risk of the Product**: The risk of the product must be acceptable.
   - **Benefit of the Product**: The benefit of the product must outweigh its risk.
   - **Characteristics of the Population**: The characteristics of the population for which the EUA is being considered must be considered.
   - **Data Requirements**: The data required for the EUA must be submitted and reviewed by the FDA.

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• The CBRN agent referred to in the HHS EUA declaration can cause a serious or life-threatening disease or condition;

• The product may be effective in diagnosing, treating, or preventing such disease or condition;

• The known and potential benefits of the use of the product outweigh its known and potential risks; and

• There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such a disease or condition.

The regulatory mechanism of EUA issuance is important, and HHS has used this mechanism effectively in the past. For example, in response to the Ebola epidemic in West Africa, EUAs were issued for a number of diagnostic tests. As of June 2015, the FDA had issued EUAs for 9 diagnostic tests for Ebola virus disease, which allowed these tests to be used during the response\(^20\). One example of this nimble EUA process is the authorization of the BioFire Defense, LLC, FilmArray Biothreat-E Ebola diagnostic. An EUA for this product was issued by the FDA just 7 days after the request was received on October 18, 2014\(^21\). Additionally, the FDA has issued EUAs for diagnostic tests for MERS Co-V, H7N9 influenza, and H1N1 influenza, as well as for H1N1 antivirals, personal protective equipment, and others to support preparedness and response\(^22\).

Not all products in the development process will meet the criteria for issuance of an EUA, nor is an EUA the only approach to enabling access to unproven MCMs. In some circumstances, the best mechanism for enabling access to investigational products in a public health emergency may be a clinical trial or expanded access (sometimes known as “compassionate use”).

In the event of a major biological attack in the United States, there would undoubtedly be public pressure to use unapproved countermeasures in an attempt to prevent or treat illness. The US government will need to balance a need for MCMs in such a scenario against the need to protect the public from harm that could come from releasing an MCM prematurely.

The US government will need to develop a process for rapidly executing scientifically sound clinical trials in the midst of an emergency in order to gather sufficient data to support broader use, when necessary, under an appropriate mechanism. Significant investments of time and money should be made in the following areas:

• Preclinical screening approaches, such as “organs-on-chips,” to expedite MCM testing and validation, or provide an advanced indication of MCM efficacy in humans\(^23\);

• Protocols and plans for the rapid conduct of clinical trials, with a focus on trials that are well-designed to provide meaningful information;

• Plans for gathering information to support EUA candidates if sufficient human data are not available or cannot be gathered in the time available; and

• Enhanced postmarket surveillance to rapidly identify problems with MCM safety and efficacy once they are in public use.

* Under the Federal Food, Drug, and Cosmetic Act, an individual patient may seek expanded access (sometimes called single-patient access or compassionate use) to investigational products for the diagnosis, monitoring, or treatment of a serious disease or condition if the specific conditions are met.
For novel diagnostic technologies, there is an additional regulatory mechanism that applies to laboratory-developed tests: the Clinical Laboratory Improvement Amendments (CLIA).\textsuperscript{24} CLIA is administered by the Centers for Medicare and Medicaid Services in collaboration with the FDA and is required for laboratory-developed tests to ensure that they are conducted properly and that results are interpreted accurately. In general, and under normal operating conditions, the higher a test’s complexity, the more unlikely it will be approved for use outside the laboratory setting.

In a Jump Start–like scenario, if a laboratory-developed test meets predefined operating characteristics that would make it useful at the point of care, it may be necessary to grant that test a CLIA waiver in order to enable its use outside of the laboratory setting. The FDA has the authority to grant a CLIA waiver for a diagnostic test or device when issuing an EUA.
Healthcare System Response

While much progress has been made in preparing hospitals and other parts of the health sector for common disasters of limited size, little progress has been made in preparing for a catastrophic health event involving thousands, hundreds of thousands, or more sick or injured people.25

A number of studies have documented that US hospitals are better prepared for a variety of common disasters as a result of efforts (local, state, and federal) made since 2001. This is evidenced by the effective response to a number of recent events such as the Boston Marathon bombing, the Aurora shootings, and the Joplin tornado. But significant gaps remain, including an inability to scale-up the healthcare response needed for a catastrophic health event. Such an event would overwhelm immediately available hospital capacity, leading to the deaths of many victims who might otherwise be saved. It would also disrupt care of “normal” patients, whose health and lives could be compromised.

Hospitals, individually and collectively, across a community, plan and practice for the kinds of disasters they are most likely to experience, such as mass trauma, severe storms, and severe influenza epidemics. But most hospitals and most communities have not seriously planned or practiced for a catastrophic disaster such as a bioattack on the scale of the Jump Start scenario. In part, this is because the needed response is much bigger than any one community can muster. In order to prepare for their small part of a national-scale response, hospitals and communities need to know their roles in a national response—what is expected of them and what they can expect from others. As yet, there is no unifying concept of operations for a national healthcare response to a catastrophic health event. Without a larger plan, it is hard for individual hospitals or communities to plan or practice their piece of it.

The problem is fundamentally one of capability and coordination rather than capacity. Bed space is not the critical issue for response to a catastrophic health event. There is much more capacity in the US healthcare system than is usually recognized. On any given day, typically only about 60% of US hospital beds are occupied. This means there are more than 100,000 available beds. But much of this capacity is in small and rural hospitals, which would need help to be useful in a national-scale response. Even in big urban hospitals, staffing may be more of an issue than beds. While numerous small disasters have shown that staffing can be readily increased for short-term acute events, maintaining high staffing levels for a prolonged period of time is a much greater challenge.

Because every hospital and every community is different, the kind of support hospitals will need in a Jump Start–like scenario will vary. Therefore, support must come in the form of a mix of available assets, including deployable specialty teams, cadres of trained local clinicians, and telemedicine. Patients will also need to be able to get to where the available beds are. This is a challenge especially for hospitals in more remote locations. The current National Ambulance Contract is insufficient in size and capability for a catastrophic health event, and the other transportation assets provided by the military cannot be assured, given they might be required in a military response. They also may take too long to be mobilized to save many lives.

* Homeland Security Presidential Directive 21 defines the term “catastrophic health event” as any natural or manmade incident, including terrorism that results in a number of ill or injured persons sufficient to overwhelm the capabilities of immediate local and regional emergency response and health care systems.
An effective response to such a catastrophic health event will require coordination among all the hospitals in a community and between hospitals and local agencies such as public health, emergency management, and emergency medical services. A great deal of progress has been made in the development of healthcare emergency preparedness coalitions focused on such collaboration, but even the best of these coalitions is not prepared for a catastrophic event such as in this scenario. To be prepared for a catastrophic health event, the coalitions would need to adapt in ways that gave them much greater capabilities; preparedness funding would need to be increased and reformed; coalitions would need to be interconnected across jurisdictions and across state lines; the federal National Disaster Medical System and Medical Reserve Corps would need to be reconfigured, strengthened, and integrated with the existing healthcare system; a national concept of operations for a catastrophic health event would need to be developed; patient transportation would need to be reconsidered; and the acceptance of foreign medical assistance would need to be made feasible.

In a Jump Start–like scenario, the following actions should be taken to assemble and connect critical pieces of the existing healthcare system and to fill known preparedness gaps.

**Create a National Health Response Concept of Operations**

A health system–specific concept of operations (conops) should be established that sets forth the roles, responsibilities, and expected actions in a catastrophic health event for each type of entity in the healthcare system (eg, hospitals, public health agencies, EMS, coalitions). As an example, Israeli hospitals all know in advance that they are expected to have 20% immediate surge capacity and that the hospitals closest to a disaster are expected to do only immediate triage, stabilization, and rapid transfer of patients to other facilities. Hospitals further from the event know to expect rapid transfers. All the hospitals know how the transfers will be coordinated and what kind of outside help can be expected. The concept of operations should build on and be consistent with existing national strategies, such as the national preparedness system. Under the direction of the Presidential Biodefence Task Force, the development of the conops should be delegated to the HHS ASPR working across agencies with relevant partners, including CDC and DHS. Development of an effective concept of operations will require the input of those entities that will actually carry out the actions. This would include representatives of the hospitals, emergency management agencies, public health departments, and EMS agencies.

**Improve, Expand, and Connect Healthcare Emergency Preparedness and Response Coalitions**

Healthcare coalitions are now the backbone of US healthcare preparedness strategy. Coalitions could be strengthened by requiring federal medical facilities (military and VA) to be active participants in local healthcare coalitions and by increasing Hospital Preparedness Program (HPP) funding to support coalitions. In a Jump Start–like scenario, HPP should increase the emphasis of coalitions on load and resource sharing and coordination. HPP should also require interconnection and coordination between neighboring coalitions. CMS should require as a condition of participation that (1) all health facilities to be part of a healthcare emergency preparedness coalition, (2) that coalitions demonstrate realistic plans for being able to achieve the goals of immediate bed availability as outlined by ASPR, and (3) that all coalitions
(and constituent members) adopt crisis standards of care plans consistent with the National Academy of Medicine (previously known as the Institute of Medicine) guidelines.  

**Augment Existing Federal Disaster Medical Programs**

**Medical Reserve Corps**—Create a new federal “medical reserve corps” (MRC) capable of providing inpatient care in local hospitals. To do this, the participating medical professionals could no longer be casual volunteers; instead, they would need to be part-time federal employees with pay, regular training, and liability protection. They would also have to be trained and credentialed at specific local hospitals. Hospitals should be required to participate with this new medical reserve corps as a condition of participation with CMS, but the hospitals would need compensation for the cost of training, either through CMS or HPP. The number and distribution of the participating medical professionals should be determined on a regional or coalition level consistent with the concept of operations described above.

**National Disaster Medical System**—Reform and reinvigorate the National Disaster Medical System (NDMS) to better integrate it into the existing healthcare sector. This would involve requiring all hospitals to participate in the definitive care part of NDMS by making it a condition of participation with CMS. NDMS should integrate its federal coordinating centers (FCC) with local healthcare coalitions to facilitate patient transfers. This would enable more efficient and appropriate distribution of patients following a catastrophe. NDMS should also create a full-time federal rapid deployment critical care force that includes critical care physicians, nurses, and technicians. These teams should respond to all disasters (foreign and domestic) and work in military and VA intensive care units in normal times. A model may be CDC’s Epidemic Intelligence Service, in which young physicians just out of fellowship training receive valuable experience over 1 to 2 years.

**Improve Mass Casualty Transportation Capabilities**

Patient transport in a catastrophic health event must be transformed. The existing National Ambulance Contract (administered by FEMA) should be expanded and made more capable with higher levels of medical care available and a more rapid deployment time. In conjunction, crisis standards of care plans for patient transportation should be developed that include use of nontraditional vehicles. These plans should be created with the input of relevant stakeholders, including representatives of the EMS, healthcare, and emergency management communities, and with the involvement of the relevant personnel from ASPR, FEMA, and the Department of Transportation. Patient tracking systems should also be enhanced and expanded.

**Enable US Acceptance of Foreign Assistance**

HHS, the State Department, and FEMA should work together to find ways to overcome current obstacles to receiving international medical assistance.
Decontamination and Remediation

Under the current biodefense posture, where a major biological attack is seen as possible but not highly likely, the US maintains a de facto policy of zero acceptable risk for decontamination following a biological attack, meaning that contaminated areas would be cleaned until no viable biological contamination is detected.

This policy was set during the 2001 anthrax letter incident (Amerithrax) in which contamination was limited by the small amount of Bacillus anthracis material contained in the letters and the relatively few indoor spaces that were contaminated. In this event, it became clear that very limited exposure to anthrax (perhaps only a few spores) could cause infection in some individuals, particularly in vulnerable individuals such as the elderly and immunocompromised. As a result, the federal government determined that no level of detectable residual contamination would be acceptable, because any contamination could result in possibly fatal infections.

This zero-spore policy was applied following the 2001 anthrax attacks through a strategy of sampling, cleaning, and resampling of small areas until no further viable spores were found. Many experts agree that a finding of zero spores did not mean residual spores did not remain elsewhere, but it did satisfy the zero viable spore detection policy at the time. Billions of dollars were spent to remediate to this standard, and still 1 contaminated building was never able to be reopened because of lingering doubt about whether the risk of infection was really reduced to zero.

It should be noted that zero risk is not the policy or goal for other decontamination/-remediation programs in the federal government. For EPA programs like Superfund and USDA/EPA programs addressing microbiological contamination in food and water, human health risk assessment and management of contamination seeks to limit human health risks, but does not seek to reduce risk to zero.\textsuperscript{28,29}

Experts have determined that with current remediation policies, an anthrax-contaminated urban area might be unusable for 2 to 14 years, and industry experts have estimated that after 6 months, businesses and residents would relocate permanently, thus potentially resulting in abandonment of portions of major US cities.\textsuperscript{30}

“The notion that there is some level of risk that everyone will find acceptable is a difficult idea to reconcile and yet, without such a baseline, how can it ever be possible to set guideline values and standards, given that life can never be risk free. . . . zero risk is completely unachievable. . . .”\textsuperscript{31(p207)}

A major barrier to progress in setting policy for biological remediation is a lack of scientific data. One particular area of scientific uncertainty is dose-response data for biological agents of concern. Because, for ethical reasons, research cannot be conducted on humans to better understand how these biological agents cause disease, there is very little reliable human data to draw on in making remediation decisions. Studies have been conducted in animal models to understand dose-response for some agents, but even these data are incomplete and uncertain, and it is difficult to extrapolate from animal data to determine effects on humans.
Another area that suffers from a lack of data and has impeded policymaking about remediation is environmental persistence. While a number of studies have and are being done by DHS, EPA, DoD, and the national laboratories to look at persistence of select agents in the environment, uncertainty in this area is still great, particularly surrounding the risks posed by potential re-aerosolization of biological agents and their ability to cause infection. Of the biological agents of concern, Bacillus anthracis is most worrisome because, in its spore form, these bacteria can persist for long periods in the environment, and studies have shown that this agent can be re-aerosolized and remain viable. Expert opinion on the risks posed by re-aerosolization is divided, and there are no public planning documents that indicate how the risks of re-aerosolization will be determined in a wide-area attack.

This section suggests strategies and offers recommendations for consideration in a decontamination/remediation response—critically important in a Jump Start–like scenario in which success or failure in remediation of major cities may make the difference between recovery and long-term public health and economic disaster.

**Develop a National Strategy, Policy, and Standards for Decontamination/Remediation**

Recent work by federal, state, local, and private sector partners has begun to address some of the unanswered operational, policy, and scientific questions on biological remediation. This work has resulted in a number of useful guidance documents to help state and local jurisdictions plan for biological remediation, new research findings on biological persistence and fate in the environment, and a roadmap to help guide science and technology research and policy in this area going forward. Most useful for national-level decision makers is the Interim Consequence Management Guidance for a Wide-Area Biological Attack, issued in 2011. However, the Interim Guidance does not offer a solution or change federal policy for decontamination standards; it does not reduce scientific uncertainty about the risks; and it does not provide an operational plan for a national approach to remediation.

Accordingly, decontamination/remediation would need to receive top priority in a Jump Start–like scenario. A senior White House led interagency group should assume responsibility for developing a national strategy, policy, standards, and priorities for decontamination/remediation.

A number of federal agencies and other stakeholders should have senior-level representation on this decontamination/remediation group: DHS, EPA, HHS, USDA, DoD, state and local public health and environmental agencies, industry, and academia, among others. The group should be composed of individuals who can make decisions on behalf of these agencies and organizations, and they will need to have sufficient subject matter expertise and reach-back capability in order to enable decisions and provide guidance.

**Build a Remediation Implementation Plan**

Using the *Interim Consequence Management Guidance* for direction, the decontamination/remediation group should draft a national-level implementation plan to aid in coordinating the large stakeholder group and the large number of tasks needed for remediation and reoccupation of a major city. This plan should
provide strategic policies and decisions about decontamination and remediation levels and approaches, assign agencies and individuals specific remediation roles and responsibilities, outline processes and mechanisms for obtaining resources, and set goals and deadlines. This plan should be reviewed and updated frequently as the situation changes and evolves.

**Set Policy on Addressing “How Clean Is Safe” Question**

Following a major bioterrorism attack anywhere in the world, and with the expectation that another attack could occur in the US imminently, the decontamination/remediation group should immediately review US policy for decontamination standards and existing scientific knowledge about agents of concern. Given the data gaps, there will be great uncertainty about decontamination of biological agents in a wide-area event, but this group would need to provide senior leaders with recommendations for critical decisions—even with imperfect knowledge.

Based on existing science, availability of medical countermeasures, and other public health, political, ethical, social, and fiscal considerations, this group should produce a set of options for decontamination standards. If possible, standards for remediation and clearance (for reoccupation) should be set in advance of a follow-on attack, so that immediate action can be taken to limit the public health and economic impacts. This will be very important, especially in a no-notice event, when minutes, hours, and days will matter in preventing exposures and saving lives.

In developing options for decontamination standards the group will need to conduct trade-off analyses to demonstrate potential impacts from decontamination policy decisions. For example, management options that include lower acceptable standards of contamination will provide greater protection of public health but will require a greater commitment of time, money, and resources to meet, potentially resulting in greater economic impacts on affected cities. The group will also need to consider local feasibility of each option to determine whether they can be realistically implemented with success.

**Reexamine Research Agenda and Expedite Research**

Simultaneously, the decontamination/remediation group should rapidly identify gaps in scientific knowledge about dose-response, environmental stability, re-aerosolization, and decontamination materials and approaches that can and should be addressed in the short term with additional research. This may include research priorities identified previously, but not conducted or completed because of a lack of resources or attention.

**Identify Companies and Individuals Who Could Carry Out Remediation**

In preparation for response to a city-wide contamination event, the decontamination/remediation group should establish a database of reputable companies that can be used to carry out decontamination of a major city. These companies will need to be quickly vetted to ensure their competence, and a mechanism will need to be established to pay or reimburse companies for their work. The decontamination/remediation group will need to make recommendations about whether the fiscal and coordination
responsibility for decontamination will rest entirely with the public sector (either state and local or federal
government), or whether private businesses will be responsible for conducting and paying for remediation,
or a combination of both approaches.

Prepare Laboratories to Test Environmental Samples

In the response to a wide-area attack on a US city, laboratories will be crucial for testing both clinical
samples and environmental samples to aid in decontamination. Currently, there are a limited number of
laboratories equipped with the means and knowledge to process environmental samples from a biological
attack. These Environmental Response Laboratory Network (ERLN) labs will need to be expanded to
include laboratories outside of the current system, and they will need to be provided with guidance,
reagents, and equipment to process biological samples for the purposes of environmental testing.
Laboratories in the private sector and in academia may be able to assist in this effort if they are provided
with the right guidance and resources.

Establish Vaccination Policy

The decontamination/remediation group will also need to develop a long-term strategy for reoccupation
of US cities following an attack. A major consideration in reoccupation will be policy on vaccine use (if there
is an available vaccine for the agent of concern). Currently, there is no policy on post-attack vaccination
for a wide-area biological attack on a US city. Because it will be impossible to remediate to a level of zero
contamination, and given that there will be residual risk to the public, if vaccine were to be available,
strategic decisions about use of vaccine to protect residents and visitors to a city will be necessary. These
decisions could have a major influence on whether a city is evacuated and abandoned or whether people
continue to live and thrive in a city post-attack.
Environmental Detection

One potential source of early warning of an attack will be environmental detection. The US currently relies on the BioWatch system as its primary approach to environmental detection of aerosolized biological releases. BioWatch air sampling units are deployed in major cities and some indoor transit hubs around the country. BioWatch filters are collected by local public health and environmental agencies each day and are processed at designated laboratories using PCR-based assays.

When a biological agent of concern is detected and confirmed from a BioWatch sample, a BioWatch Actionable Result (BAR) is declared, which leads to deliberation and analysis by public health officials and actions to protect the public if it is determined that an attack has taken place.

The BioWatch system has limitations: It takes time to collect and process samples, which may lead to delays in recognition of an attack; it is deployed in relatively few locations; and it cannot provide the precise time, amount, geographic distribution, or direction of a biological release. A BioWatch Actionable Result does not automatically trigger an immediate response from public health officials. This is because responses are usually “high-regret”—that is, there can be major social, economic, ethical, and public health repercussions of response actions—and thus require greater certainty than a BioWatch Actionable Result alone can provide. Finally, the recently developed Generation 3 BioWatch system, which was intended to reduce time to detection through automated sample preparation and processing inside the collection device, was piloted but never fully implemented because of challenges with cost, sustainability, and reliability.

Other environmental detection technologies have been discussed, and in some cases deployed, including light detection and ranging (lidar) technologies at the Pentagon. However, the widely deployed environmental detection technology for biological agents now in use is BioWatch.

In a Jump Start–like scenario, where one major biological attack has already occurred and reload is anticipated, rapid detection of any follow-on attacks will be important. This section recommends actions related to environmental detection that might speed recognition of an attack.

Expedite and Expand BioWatch Collection and Processing

In anticipation of follow-on attacks, there will be a strong demand for expanding the use of biological detection and surveillance systems in order to increase the probability of early detection. There is scientific debate now regarding the value of the BioWatch program in detecting attacks and, should detection occur, in the likelihood that action would be taken on the basis of positive results. Lessons from states and cities with experience in responding to BioWatch Actionable Results and in conducting operational BioWatch drills should be gathered and incorporated into decision making. The Presidential Biodefense Task Force will need to carefully consider approaches and technologies that could best be used to augment the current biodetection infrastructure.

In the immediate aftermath of a Jump Start–like scenario, enhancement of existing biodetection systems would be a logical first step, even with the uncertainties regarding the BioWatch system. In particular,
increasing the frequency of BioWatch filter collection and processing for existing units could potentially reduce the time to recognition that an attack has occurred. This increase in frequency could, in principle, be implemented rapidly, though it would require significant personnel time and resources from public health agencies and laboratories to collect, transport, and process the large number of samples. 

Assessment would need to be made regarding whether public health agencies and labs have the people and equipment in place to increase the frequency of filter collection and processing before decisions are made to do so. One possible step would be to revisit the Gen 3 BioWatch technology in order to understand whether Gen 3 might be able to help meet immediate needs for environmental detection with limited alterations to the system and additional funding. Technical details of this technology’s testing performance—not available in the public domain or to the authors of this report—would need to be examined to make that kind of determination.

**Evaluate Additional Detection Technologies for Use**

Over the longer term, detection technologies should be evaluated that might provide complementary environmental detection capabilities either in the field or in the lab. Such potentially useful technologies that should be evaluated would likely include sensors for wide area (nonspecific) detection of aerosolized materials (eg, lidar or hyperspectral imaging); other remote or handheld sensor technologies (similar to BioWatch) that collect samples and provide preliminary identification of biological agents; and sequencing technologies that can provide confirmation of the presence of specific biological agents. In evaluating technologies for the medium term, emphasis should be placed on making them operationally useful. Each technology will need to have an accompanying concept of operations and be accurate, reliable, and user-friendly for public health officials and decision makers if they are to be implemented successfully.

**Accelerate Research and Development for New Detection Technologies**

For the long term, research and development should focus on advancing technologies that provide better, faster, more accurate environmental detection. Ideal requirements of usable future detection technologies include:

- Nearly 100% sensitivity and specificity for the biological agents of concern;
- Ability to distinguish background contamination from aberration;
- Capability for continuous monitoring of major population centers and high-value targets;
- Ability to detect and characterize a biological plume in near real time;
- Reliable estimation of the population at risk or exposed in a release;
- Triggers that automatically alert the appropriate decision makers; and
- Low cost and easy maintenance.
Conclusion

A large-scale biological attack, or campaign of attacks, against one or more US cities could lead to catastrophe, both in terms of lives lost and in economic and societal disruption. However, it is within the power of the US government to mitigate the consequences of a biological crisis through effective leadership, policy, research, and emergency response. The recommendations contained in this report reflect the best judgement of biodefense experts about what actions can and should be taken to reduce the impact of a national biological incident. If the recommendations in this report are fully implemented, the effects of a biological attack on this country could be significantly reduced.
References


Appendix A: Jump Start Senior Advisors


Rob Carlson, PhD, is the Managing Director of Bioeconomy Capital. He previously served as a Senior Lecturer in the Department of Computer Science and Engineering at the University of Washington, and as a Research Fellow at the Molecular Sciences Institute in Berkeley, CA.

Richard Danzig, JD, PhD, is the Vice Chair of the Board of Trustees of the RAND Corporation, a member of the Defense Policy Board and the President’s Intelligence Advisory Board, and a Director of the Center for a New American Security. He previously served as the 71st Secretary of the US Navy in the Clinton Administration.

Noreen Hynes, MD, MPH, currently serves on the National Preparedness and Response Science Board at HHS. She previously served as Senior Advisor to the Vice President for Medicine and Public Health (Homeland Security Affairs) and Deputy Assistant Secretary of Health for Preparedness and Response from 2001 to 2003.

David McIntyre, PhD, previously served as the Dean of Academics and Faculty at the National War College, deputy director of the ANSER Institute for Homeland Security, and director of a graduate program in homeland security at Texas A&M University.

Matthew Minson, MD, is the Senior Advisor for Health Affairs for the Texas Engineering Extension Service, and at the Texas A&M University Health Science Center. He previously served as the Senior Medical Officer for Strategic Initiatives at ASPR and as the Director of Office Preparedness and Response at the State of Maryland’s Department of Health and Mental Hygiene.

Michael T. Osterholm, PhD, MPH, is McKnight Presidential Endowed Chair in Public Health at the University of Minnesota, director of the Center for Infectious Disease Research and Policy (CIDRAP), and a professor in the Division of Environmental Health Sciences, School of Public Health. He previously served in the Minnesota Department of Health as the State Epidemiologist and chief of acute disease epidemiology.

Major General Stephen Reeves, US Army (Ret), established and previously served as the Joint Program Executive Officer for Chemical and Biological Defense, where he was responsible for all DoD chemical and biological defense countermeasures. He is currently a member of the Preparedness Leadership Council, International, focused on addressing and preparing leaders for the changing global threat environment.
Appendix B: Jump Start Interviewees

Interviews were conducted and positions are current as of May 2014-January 2015.

Amesh Adalja, MD
Senior Associate, UPMC Center for Health Security; Clinical Assistant Professor, Department of Critical Care Medicine, University of Pittsburgh School of Medicine and UPMC

Charles Allen
Former Assistant Director of Central Intelligence for Collection, Central Intelligence Agency; Under Secretary for Intelligence and Analysis, US Department of Homeland Security

Major General Donna Barbisch, DHA, MPH, USA (Ret)
President, Global Deterrence Alternatives; Director, Institute for Global and Regional Readiness

Luke Beckman
Manager, Situational Awareness, American Red Cross; Fellow (2014), Emerging Leaders in Biosecurity

Kenneth Bernard, MD
Former Senior Political Advisor to the Director-General, World Health Organization; former Special Assistant to the President for Biodefense, Homeland Security Council, White House

Luciana Borio, MD
Acting Chief Scientist, US Food and Drug Administration; Assistant Commissioner for Counterterrorism Policy

Patrick Boyle, PhD
Gingko Bioworks; Fellow (2014), Emerging Leaders in Biosecurity

Joseph Buccina
Senior Associate, Public Health Strategy and Operations Team, PricewaterhouseCoopers; Fellow (2014), Emerging Leaders in Biosecurity

Elin Carlin, DVM
Principal, Carlin Communications; Senior Professional Staff, House Committee on Homeland Security

Rob Carlson, PhD
Managing Director, Bioeconomy Capital; Senior Scientist, Electrical Engineering Department, University of Washington

Richard Carmona, MD, MPH
Surgeon General of the United States

Elizabeth Carter, MPH
Senior Director, Chertoff Group; Fellow (2014), Emerging Leaders in Biosecurity

W. Seth Carus, PhD
Distinguished Research Fellow, Center for the Study of Weapons of Mass Destruction, National Defense University

Bruce Clements, MPH
Preparedness Director, Texas Department of State Health Services; Public Health Preparedness Director, Missouri Department of Health and Senior Services

Alan Cohen, JD
Assistant Secretary for Strategy, Planning, Analysis & Risk, Office of Policy, Department of Homeland Security

Craig Collier
Senior Director, Planning Disaster Cycle Services, American Red Cross

Richard Danzig, JD, PhD
Director, Center for a New American Security; member, Defense Policy Board; former Secretary of the US Navy

Annie Degroot, MD
Research Professor and Director, Institute for Immunology and Informatics; CEO, Epivax, Inc

Chas Eby, MA
Chief Planner for Public Health, Maryland Department of Health and Mental Hygiene; Fellow, (2014), Emerging Leaders in Biosecurity.
Gerald Epstein, PhD  
Deputy Assistant Secretary for Chemical, Biological, Radiological, and Nuclear Policy, Office of Policy Implementation and Integration, Office of Policy, US Department of Homeland Security

Rebecca Fish, MBA  
Senior Policy Advisor to the Deputy Assistant Secretary of Health and Director of the National Vaccine Program Office; Fellow (2014), Emerging Leaders in Biosecurity

David Franz, DVM, PhD  
Former Commander of the US Army Medical Research Institute of Infectious Diseases (USAMRIID); former Deputy Commander of the Medical Research and Materiel Command

Elizabeth George, PhD  
Director, Cooperative Threat Reduction Directorate, Defense Threat Reduction Agency; Director, Department of Homeland Security, Chemical and Biological Defense Division, Science and Technology Directorate

John Grabenstein, PhD  
Executive Director, Global Health & Medical Affairs, Merck Vaccines

Ellie Graeden, PhD  
Director of Strategic Systems Analysis, Gryphon Scientific; Fellow (2014), Emerging Leaders in Biosecurity

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Appendix C: Interview Guide - Key Issues

Governance

- Who will be in charge of a large-scale response in a multijurisdictional region?
- Would this scenario require the use of the Defense Production Act of 1950?
- Would intellectual property law impede a timely response for MCM development?
- Are current liability protections adequate?
- Are the current contracting procedures adequate?
- Is the current Emergency Use Authorization sufficient?

Science & Technology of Bioresponse

- What technologies are available to provide rapid development and deployment of diagnostic capabilities for known and novel diseases?
- How can we best leverage genetic/synthetic bioengineering and improved traditional methods for rapid development of new medical countermeasures (eg, vaccines and therapeutics to include monoclonal antibodies and phages)?
- Can leading-edge technologies (eg, organ on a chip) provide capabilities to significantly improve rapid medical countermeasure approval?
- What can be done to rapidly improve capabilities for microbial forensics and attribution?
- What can be done to rapidly improve capabilities for large-area decontamination of anthrax?
- What emerging technologies can be leveraged to improve resilience and public health response (eg, mHealth, advanced modeling, “big data”)?

Operational Processes

- What more could be done to improve the capability for rapidly distributing and dispensing medical countermeasures?
- How can the resources of the VA (America’s largest healthcare provider) be used in responding to a domestic attack (beyond caring for veterans who may be casualties)?
- What could be done to significantly improve real-time data sharing on medical countermeasure performance?
- What more could be done to significantly improve medical surge capacity and capability to deal with tens of thousands of ill patients needing hospital care (many of whom may be critically ill) and hundreds of thousands (or millions) needing medical screening, prophylaxis or minor outpatient care (eg, hospital preparedness, crisis standards of care, allocation of scarce resources)?
- What more could be done to significantly improve effective public messaging and public communication via traditional and social media?
- What could be done to significantly improve public health situational awareness for this kind of event?
- What could be done to significantly improve global supply chain response needs, particularly relating to sustaining supplies of medical countermeasures during supply-shocks and maintaining supply of key active pharmaceutical ingredients and bulk chemicals?
- What more can be done to enable large numbers of sick patients to be effectively distributed and transported throughout the country to places where they can get needed care?
- What could be done to significantly improve global supply chain response needs, particularly relating to sustaining supplies of medical countermeasures during supply-shocks and maintaining supply of key active pharmaceutical ingredients and bulk chemicals?
The following list identifies 51 presidentially appointed, Senate-confirmed positions that have significant responsibility for biodefense preparedness and/or response, particularly in a Jump Start–like scenario. It is provided to demonstrate the complexity of the biodefense enterprise in the federal government.

It should be noted that many key players in biodefense are not presidentially appointed and Senate-confirmed, including the Director of the Centers for Disease Control and Prevention (HHS), the Director of the Biomedical Advanced Research and Development Authority (HHS), the Assistant Commissioner for Counterterrorism Policy (FDA), Chief Scientist (FDA), the Director of the Office of Biodefense Research Affairs and Associate Director for Biodefense Product Development (NIH), National Security Staff (NSC), the Assistant Director of Weapons of Mass Destruction Directorate (FBI), and many others. Additionally, presidentially appointed, Senate-confirmed leaders in the intelligence community, who would play major roles in a Jump Start–like scenario, were not included in the list below.

Based on the research conducted for the Jump Start report and a 2004 report on biodefense leadership, the total number of senior biodefense leaders in the federal government, spread across a dozen organizations, most likely exceeds 100.

### Appendix D: Federal Biodefense Positions

**Department of Health and Human Services**
- Secretary
- Deputy Secretary
- Administrator, Centers for Medicare and Medicaid Services
- Assistant Secretary, Resources and Technology
- Assistant Secretary for Preparedness and Response
- Assistant Secretary, Planning and Evaluation
- Commissioner of Food and Drugs
- Director, National Institutes of Health
- Surgeon General

**Department of Homeland Security**
- Secretary
- Deputy Secretary
- Under Secretary for Science and Technology
- Under Secretary, National Protection and Programs
- Assistant Secretary, Policy
- Administrator, Federal Emergency Management Agency (FEMA)
- Deputy Administrator, FEMA
- Deputy Administrator, Protection and National Preparedness (FEMA)

**Environmental Protection Agency**
- Administrator
- Deputy Administrator
- Assistant Administrator, Research and Development
- Assistant Administrator, Solid Waste and Emergency Response
- Assistant Administrator, Water
Department of Defense
- Secretary
- Deputy Secretary
- Assistant to the Secretary for Nuclear and Chemical and Biological Defense Programs
- Assistant Secretary for Health Affairs
- Under Secretary, Policy
- Assistant Secretary, Homeland Defense and America's Security Affairs
- Director, Defense Research and Engineering
- Commander North American Command

Department of Agriculture
- Secretary
- Deputy Secretary
- Under Secretary, Food Safety

Department of Justice
- Attorney General
- Deputy Attorney General
- Assistant Attorney General, National Security Division
- Director, Federal Bureau of Investigation

Department of Veterans Affairs
- Secretary
- Deputy Secretary
- Assistant Secretary, Policy and Planning

Office of Science and Technology Policy (Executive Office of the President)
- Director
- Associate Director, Science
- Associate Director, Technology
- Associate Director, National Security

Department of State
- Secretary
- Deputy Secretary
- Assistant Secretary, Oceans and International Environmental and Scientific Affairs
- Assistant Secretary, Arms Control, Verification and Compliance
- Assistant Secretary, International Security and Nonproliferation
- Ambassador-at-Large, Coordinator, Counterterrorism

Department of Treasury
- Assistant Secretary, Terrorism and Financial Crimes
Acknowledgments

This year-long study and our report could not have been accomplished without the financial support of the Smith Richardson Foundation, and UPMC; the cooperation of the 71 interviewees who gave of their valuable time; and our 8 senior advisors, who provided assistance in study design and review and comments on this final report.

The authors of this report wish to give special thanks to Ryan Morhard, JD, for his exceptional work during the first 4 months of this study prior to his move to the US Department of Health and Human Services.

We greatly appreciate the artwork and layout design by Davia Lilly at Lilly Design Group, and editorial work by Jackie Fox at the UPMC Center for Health Security.