

## SPECIAL FEATURE

# BIOSECURITY MEMOS TO THE OBAMA ADMINISTRATION

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On inauguration day, President Obama posted his administration's biosecurity priorities on the White House website. They are:

- **Prevent Bioterror Attacks:** Strengthen U.S. intelligence collection overseas to identify and interdict would-be bioterrorists before they strike.
- **Build Capacity to Mitigate the Consequences of Bioterror Attacks:** Ensure that decision makers have the information and communication tools they need to manage disease outbreaks by linking healthcare providers, hospitals, and public health agencies. A well-planned, well-rehearsed, and rapidly executed epidemic response can dramatically diminish the consequences of biological attacks.
- **Accelerate the Development of New Medicines, Vaccines, and Production Capabilities:** Build on America's unparalleled talent to create new drugs, vaccines, and diagnostic tests and to manufacture them more quickly and efficiently.
- **Lead an International Effort to Diminish Impact of Major Infectious Disease Epidemics:** Promote international efforts to develop new diagnostics, vaccines, and medicines that will be available and affordable in all parts of the world.

The memos that follow from the Center for Biosecurity of UPMC offer views on an array of biosecurity challenges confronting the Obama Administration. The first offers recommendations regarding strategic priorities for U.S. biosecurity. The memos that follow provide program recommendations in key areas: the biosecurity budget, prevention, biosurveillance, medical preparedness, public health preparedness, community engagement, and medical countermeasure development and manufacturing.

These memos are intended to be of strategic and pragmatic value for the incoming officials in the Obama Administration who have responsibility for biosecurity in the White House and in the federal agencies.

## STRATEGIC PRIORITIES FOR U.S. BIOSECURITY

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**T**he U.S. GOVERNMENT TODAY CONFRONTS an array of urgent crises of potentially great consequence. With his early leadership on pandemic influenza preparedness, in his campaign remarks regarding 21<sup>st</sup> century threats, and in statements on biosecurity on the White House website, President Obama has indicated that biosecurity is among the most important issues on the long, daunting list of national security threats he will address.

The *World at Risk* report, mandated by the 9/11 Com-

mission legislation, echoes recent National Intelligence Council assessments that a bioterror attack and terrorist use of a nuclear weapon pose the greatest potential catastrophic terrorist threats, with a bioattack being more likely. Putting in place the necessary prevention and response capabilities will require White House leadership and a steady effort on the part of Congress and the states. Below we offer some suggestions on how the U.S. ought to proceed to strengthen biosecurity.

► **President Obama and his senior advisors and government officials should make clear that they regard biological threats and the creation of a robust biodefense to be top national security priorities.**

There exists confusion in parts of the executive branch, in Congress, and in state governments about the importance and urgency of the bioterrorism threat. This confusion exists in spite of a decade-long litany of government assessments, reports by prestigious commissions, and independent analyses that have been quite clear on these issues. Taken together, these reports conclude that there are no technical barriers that prevent state programs, nonstate groups, or individuals from building and using a biological weapon that could sicken or kill as many as tens of thousands of people or more, and that could lead to grave societal disruption and economic damage. The National Intelligence Council, writing on behalf of the entire intelligence community, has said that biological weapons pose the greatest WMD threat to the country. The effectiveness of biological weapons was demonstrated by a number of state bioweapons programs in the 1960s and 1970s (including the U.S. program that was then terminated by President Nixon), which tested bioweapons on a large scale. In the nearly 40 years since, biotechnology has become more global, more accessible, and more powerful. We are in the midst of a biotechnology revolution driven by an explosion of knowledge and technologies, global capital markets, and powerful information technology tools.

Some policymakers seem to believe that definitive, *tactical* intelligence showing adversaries are in the process of preparing to launch bioattacks against the U.S. should be the trigger for making substantive investments in biodefense. But members of the intelligence community have cautioned that it is unlikely that we will receive such tactical warning of a bioterror attack. Gathering specific intelligence against the biological threat is particularly challenging, as CIA Director Leon Panetta noted in testimony during his confirmation hearing. There are no easily identifiable footprints marking bioweapons development. The work needed to develop a biological weapon is nearly indistinguishable from legitimate biological science and biotechnology, and such efforts are easily hidden in plain sight.

The U.S. already has sufficient intelligence to establish that biological weapons pose a *strategic* threat to the country. The potential consequences of biological attacks are of a scale larger than any other form of terrorist attack except nuclear weapons. Al Qaeda, and possibly other terrorist groups, have the intent to acquire and use biological weapons in such attacks. In 2002, U.S. armed forces destroyed an Al Qaeda bioweapons lab in Afghanistan before it became operational. Multiple nation states are suspected of having biological weapons development programs.

Moreover, any developed country now has the biotechnological capacity to establish a bioweapons capability in short order should it decide to do so.

The intelligence community should pursue better means of gathering intelligence on biological threats, and they deserve more top-level support and funding for this work. But as members of the intelligence community have advised, leaders should not count on getting tactical warning of a planned bioterror attack or depend solely on our ability to interdict or thwart such attacks. We have had all the warning we need to commit to a substantial strengthening of U.S. biosecurity.

In addition to strengthening our intelligence efforts, there are a series of actions and programs that would improve prevention efforts and that we should pursue more vigorously. They are briefly outlined in a memo that follows titled “Preventing the Development and Use of Biological Weapons.” Even as we pursue these efforts, we must recognize that such prevention efforts provide only partial barriers and deterrence against biological attacks. For that reason, the country must build the strongest feasible response to biological attacks, accelerating the development and manufacture of medicines and vaccines, improving our hospital and public health response, and devising and practicing the plans we have to deal with such events.

► **Establishing a “concept of operations” plan to guide the response to public health emergencies of national significance—and to avoid a BioKatrina—should be among the Obama Administration’s top tier near-term priorities.**

The Administration should rapidly develop a nationwide “concept of operations” (“con-ops”) that maps out how federal, state, and local governments and critical private sector actors would respond to a bioattack or to other public health emergencies of national significance. The U.S. does not yet have a working plan to mobilize all useful national assets in response to a big disaster involving large numbers of sick or injured people. The National Response Plan does not accomplish this. States and cities have plans for responding to bioterror attacks or pandemic flu, but these vary widely in scope, specificity, and feasibility, and most do not integrate medical response with other jurisdictions in the region. If the U.S. were to experience a bioattack today—or if a flu pandemic or a novel epidemic contagious disease were to emerge—some cities and regions would perform better than others, but we do not have a plan to bring all national assets to bear.

Many of the response components essential to diminishing the toll of a bioterror attack or natural epidemic pose daunting challenges. For example, no city or region could provide the healthcare “surge capacity” that would be needed for a response to a catastrophic health emergency. Solving the problem of how to rapidly distribute antibiotics

to tens of thousands of people after an anthrax attack is another big operational challenge. We lack the necessary medicines and vaccines for many types of catastrophic health emergencies, and the supply chains of equipment and materials needed to care for the sick could be interrupted.

Multiple agencies and authorities in the federal government have responsibility for parts of U.S. biosecurity, and there are more than 20 Congressional committees and subcommittees involved in some aspect of biodefense and biosecurity. Moreover, the great weight of responsibility for response rests with state and local governments and the private sector. The critical services that would have to be maintained in the wake of a bioattack are primarily private sector assets. Devising a plan that incorporates and integrates all these entities and that anticipates a range of possible scenarios is what is now necessary.

The Administration should make clear who in the government has top responsibility for the development of a con-ops plan for public health emergencies of national significance. The nascent effort underway in the Department of Homeland Security (spurred by Bob Kadlec in the last months of the Bush Administration) should be expanded. The different “response components” (eg, detecting and characterizing the attack, maintaining situational awareness, caring for the sick, protecting the well) should be articulated and mapped in as much detail as is possible and practical. As part of this, the federal government should define more clearly what is expected of state governments in such events and what services, functions, and materiel the federal government can be expected to provide. In the coming months, governors and state officials will be sorely tempted to cut funding and positions devoted to disaster preparedness and response. Unless there is some recognition of what constitutes “bottom line preparedness” for states and cities, much of the progress that has been achieved since 9/11, the anthrax attacks, and Katrina will be lost.

A demonstrated national capacity to respond effectively to major biological threats would not only prevent large numbers of casualties in the event of such attacks, but it may also help to serve as a deterrent against them.

► **The White House should ensure that biosecurity programs are adequately funded, coordinated across the federal agencies, and better connected with state and local governments and the private sector.**

Assuring U.S. biosecurity is not a top mission of any federal cabinet agency. Prevention, preparedness, and response activities important to the country’s ability to thwart, detect, and respond to a catastrophic health event are distributed across multiple agencies and budgets. The country needs a national biosecurity strategy that spells out our near- and long-term biosecurity objectives and assigns responsibility and authority for meeting these goals.

In the meantime, it would be valuable if OMB were to mandate a detailed cross-cut of the biosecurity budgets across the agencies, which would reveal significant gaps and redundancies in current spending and would allow a more rational assessment of investments in biosecurity compared with what we spend on various national defense projects and programs, such as fixed-wing fighter jets or missile defense. The exercise of assembling a comprehensive picture of biodefense spending would also aid interagency coordination of these important programs and initiatives.

The Administration and Congress should consider placing the biodefense programs in HHS, DHS, and other agencies on a 2- or 3-year budget cycle, to allow better planning and execution of these vital national security programs. The federal government should reexamine the funding of preparedness programs at the state and local levels and commit the federal government to some baseline amount of funding to ensure that essential capacities are there when the country needs them. If biosecurity is the national security priority that national leaders and numerous commissions and assessments judge it to be, then planning must become more disciplined and farsighted. The biothreat will not disappear, even if Al Qaeda were to be defeated and destroyed. The biothreat will only grow as the understanding of biological systems and how to manipulate them increases rapidly around the world.

► **The Administration should set a long-term strategy for the development and production of anti-infective medicines and vaccines and diagnostic tests.**

Medicines and vaccines that effectively treat and prevent the diseases caused by biological weapons or naturally occurring epidemic disease such as pandemic influenza are essential to biosecurity. The government has established programs in HHS to fund and manage the research, development, manufacture, and procurement of medical countermeasures (MCMs) for the civilian population. Biodefense-related medicines and vaccines also are being developed for the military by DoD. Thanks to robust investments in flu preparedness, there has been enormous progress in creating vaccines against H5N1 influenza—progress that might convert a potential calamity into a manageable event.

To make similar progress more broadly against the range of top biological threats requires a strategy to substantially accelerate the development and manufacture of vaccines and medicines to counter these threats. The elements of this strategy include: (1) providing adequate funding for the mission—to date BARDA funding has been wholly inadequate; (2) ensuring biodefense basic science research links to an overall plan to meet U.S. biodefense needs and requirements, both civilian and military; and (3) establishing more effective partnerships between the U.S. govern-

ment and the biopharma industry to deal with regulatory issues, technical problems, the aggregation of development and manufacturing expertise, and the like.

Ensuring that Americans have access to the medicines and vaccines they need after a bioattack or a naturally occurring epidemic will require substantial long-term commitment, funding, coordination of federal programs, and better partnerships with academia and industry. A well-informed and engaged Congress is critical to the success of this work. This will require substantial gains in the capacity to rapidly and less expensively make vaccines and medicines for established biological threats as well as for threats that might arise from nature or be deliberately engineered as weapons. Such progress would position the country to make enormous, unprecedented contributions to global health. In 1940, FDR called the U.S. “the arsenal of democracy.” The Obama Administration has the opportunity to propel this work forward in a way that could enable the U.S. to serve as a global *arsenal of public health*.

► **The Administration should recognize that a wise biodefense strategy could provide a powerful source of technological innovation and economic stimulus.**

There is no question that biosecurity policy and programs are critical to U.S. national security. The biosecurity pol-

icy priorities set forth by the Obama Administration also have potential to create strong economic stimulus. State and local public health agency funding is not only crucial for preparedness programs, it also provides salary support for health officials around the country, and loss of this funding would eliminate a substantial portion of that workforce. Hospital preparedness programs are critical to improving hospital readiness for disasters, and around the country they have built a discipline of professionals whose jobs would be gone without this support. Building digital linkages between hospitals and state and local public health agencies is not only necessary for responding to natural or deliberate epidemics, but should be part of the President’s initiative to create nationwide electronic health records for delivery of health care. Medicine and vaccine development funding is not only critical for biosecurity but provides funding to scientists working in academia and industry on new approaches to fighting infectious diseases. Taken together, these and other programs build and sustain infrastructure the country needs, provide stimulus and job growth to important sectors of the economy, and, most importantly, will strengthen the national security of the country against present and future biological threats.

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