

SPECIAL FEATURE

BIOSECURITY MEMOS TO THE OBAMA ADMINISTRATION

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

The 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 21st 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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FUNDING BIODEFENSE

SUBSTANTIAL U.S. BIODEFENSE PROGRAMS exist in 7 federal agencies, with HHS accounting for two-thirds of the total, followed by DHS (18%) and DoD (11%). The other agencies with sizable biodefense programs include the USDA, EPA, the State Department, and the National Science Foundation. Smaller biodefense programs exist elsewhere in the federal government.

Many, if not most, “biodefense” expenditures serve multiple purposes. Work done to improve the ability of local public health agencies to cope with a bioterror attack also serves to improve response to natural epidemics and to public health emergencies generally. Hospital preparedness programs are designed to increase hospitals’ ability to care for mass casualties, whatever the cause of the illnesses or injuries. Biosurveillance efforts are intended to strengthen the nation’s capacity to detect disease outbreaks before they expand beyond control, and these systems also provide decision makers with better situational awareness during disasters of many kinds.

The task of tracking and assessing the effects of federal biodefense funding is made especially difficult because of the number of federal agencies with responsibility for different aspects of U.S. biodefense, the variety of programs and initiatives that have direct bearing on biodefense preparedness and response, and the reality that much of the federal funding is directed to activities carried out at the state and local levels, making exact accounts of federal expenditures and their effectiveness problematic.

President Obama has highlighted the need to strengthen biosecurity as one of his top homeland security priorities. To accomplish this goal, agency biodefense budgets must be made more transparent and easy to identify, and the organization and coordination of overall federal biodefense expenditures should be reviewed and improved.

Recommendations

► **Increase transparency of biodefense budgets.**

Since 2001, federal agencies have become somewhat more transparent in their budgeting and accounting for biodefense programs, but most agencies do not specifically highlight biodefense in their budgets.

Moreover, the 1-year budget cycles imposed on all federal agencies (except DoD) make it virtually impossible to coherently plan or effectively execute or assess many biodefense programs. If defense against potentially destabilizing epidemics is truly considered a national security priority, federal planning, execution, and assessment of biodefense programs should have the longer planning horizon and budget cycles currently in place for DoD programs. At a minimum, critical biodefense preparation and response programs should have 2-year planning and budget cycles. Programs should be tied to specific national security goals and subjected to regular progress assessments.

Thus far, neither the Office of Management and Budget (OMB) nor the Congressional Budget Office (CBO) has assumed responsibility for accounting for biodefense funding across the federal government. As a result, the White House cannot know how much is being spent on this critical national security priority. Without more budget transparency, it will be impossible to establish true priorities, identify gaps, eliminate redundancies, or determine the impact of the money spent on biodefense.

The White House, in coordination with OMB, should prepare annual reports on the combined federal biodefense budget and should require that individual agencies more clearly separate out biodefense programs in their annual budgets-in-brief to make identification and tracking of biodefense funds easier government-wide.

► **Review the organization of civilian biodefense strategy and programs.**

After the anthrax attacks of 2001, the Bush Administration initiated a range of biodefense initiatives and also greatly increased federal and state funding for existing biodefense programs begun during the Clinton Administration. Many of these programs have accomplished a great deal and have been critical to advancing disaster preparedness, response, and mitigation capabilities. There is, however, no overall strategic plan for the U.S. biosecurity effort. Civilian biodefense remains an array of programs and projects, not tightly coordinated, and spread across multiple agencies and congressional committees.

The Obama Administration regards biodefense and biosecurity as a national security priority, but there is little evidence that the agencies responsible for biodefense programs regard biosecurity as a core mission, insofar as agency priorities are reflected in budgets or the time cabinet heads spend on issues. Interagency rivalry on biodefense matters is common; top-level coordination and the resources and leadership required for sustained interagency collaboration are rare. The sprawling array of congressional committees with jurisdiction over bits and pieces of the biodefense budget also detracts from strategic coherence or efficient, government-wide mission execution.

The Executive Office of the President should devise a clear biosecurity strategy: an explicit articulation of our national biodefense goals and priorities; clear assignments of roles, responsibilities, and authorities to specific agencies; and designation of someone in the Executive Office of the President with overall responsibility for strategic oversight and coordination. Absent such strategic direction and coordination, U.S. biodefense will continue to be a collection of programs whose shortcomings and disconnects may be recognized only when they are needed in the midst of potential crisis.

Crystal Franco

PREVENTING THE DEVELOPMENT AND USE OF BIOLOGICAL WEAPONS

PREVENTING THE DEVELOPMENT AND USE of biological weapons should continue to be a top priority for the country. There are fundamental issues that make prevention a difficult challenge. The knowledge, materials, and technologies needed to make and use a biological weapon are readily accessible around the world. Pathogens are ubiquitous in nature and can be found in hospital and research laboratories, in culture collections, and in sick people and animals everywhere. The skills and equipment for making a biological weapon are the same as those required for progress in medicine, agriculture, and other fields, so they cannot be locked away. It is now possible to synthesize viruses from nonliving components, with technologies that are becoming cheaper and widespread. Efforts that might be useful in deterring state-sponsored biological weapons programs may have little or no effect in slowing the development of biological weapons by terrorist groups.

In spite of these challenges, there are approaches the U.S. government should take that may increase the chances that we will prevent biological attacks: maintaining international norms and improving surveillance systems, deterring potential adversaries by demonstrating a strong national response, developing better forensic analysis, generating better intelligence, and implementing sensible laboratory practices and security.

Recommendations

► **The U.S. should strongly support the Biological Weapons Convention and other international treaties that prevent terrorism.**

The cornerstone of biological nonproliferation strategies is the Biological Weapons Convention (BWC)—the first agreement among nations that declared an entire category of weapons to be off-limits. The moral force of the treaty has not prevented all of its signatories from developing biological weapons: for example, the Soviet Union, a signatory to the Convention, established an enormous secret bioweapons program during the Cold War, and there are some current signatories to the BWC that the U.S. government judges to have

an offensive biological weapons program. However, it is worth noting that no country openly goes against the international norm and displays an offensive biological weapons capability. This prohibition against biological weapons development should continue to be strengthened with vigorous U.S. support to promote universal adoption of the treaty and with implementation support to other signatories.

Other international agreements intended to prevent terrorism, such as UN Resolution 1540, and measures such as the International Health Regulations (IHR) that seek to limit the medical consequences of an epidemic, also should be actively promoted by the U.S. government. The U.S. should work with these international regimes to bolster bio-surveillance, forensics, training, and biosafety—all measures that could lessen the likelihood of biological weapons development and use.

► **The U.S. should strengthen deterrence of biological weapons by expanding our ability to reduce the consequences of such attacks and by increasing investments in microbial forensics capacities.**

The consequences of a biological attack can be reduced significantly by a rapid medical response to detect, treat, and provide appropriate medical care. If the U.S. has the demonstrated capacity to seriously limit the consequences of a biological weapons attack through a rapid and effective response, this may deter some adversaries from pursuing a biological attack. In addition to this form of deterrence, the U.S. should press ahead with efforts to strengthen its microbial forensics capacity. The nation needs to develop the strongest possible scientific capacity to trace back a pathogen to its natural or laboratory origin—an important part of attributing an attack to its source.

► **The U.S. should support private sector efforts to develop international standards for genomics screening.**

Commercial gene foundries have formed 2 international industry associations to develop standards for screening cus-

tomers orders. The U.S. government should encourage and fund these private sector efforts to expand screening internationally. The goal should be to have all major international gene foundries screen their orders so that all gene orders, from Kansas City to Karachi, are screened using the most updated software.

This should be driven by the private sector for several reasons: (1) gene synthesis is an international business and so will not be subject to U.S. regulation; (2) synthesis technologies are rapidly becoming more accessible to individual laboratories, so scientists will decide to make their own genes if it becomes too onerous to go through a commercial supplier (they will likely do so at some point in any case as costs come down); and (3) the necessary software will need to evolve at speeds greater than formal regulation. Some have called for a U.S. government–curated list of approved sequences or even government-sanctioned screening software for these companies. But a top-down government-led approach would likely rapidly become irrelevant in this fast-paced technological field, very few members of which are part of the government.

► **Intelligence collection should be strengthened to identify and interdict would-be bioterrorists before an attack.**

In 2005, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction stated that the biological weapons threat is the “mass casualty threat the [intelligence community] is least prepared to face.” Making progress will require placing a higher priority on U.S. intelligence collection against biological threats, finding better ways to reward bioscientific expertise and analytic skills in the intelligence community, building better coordination between the intelligence community and the scientific and health communities, and providing more resources to the intelligence community for these efforts.

► **The U.S. should carefully evaluate new laboratory security measures to preserve the long-term security goals of medical countermeasure availability.**

Recent calls for increased laboratory security by the *World at Risk* report by the WMD Commission should be carefully considered before action is taken. Laboratory security is critical, and it has increased substantially as a result of a series of changes that have been made since the anthrax letter attacks of 2001. But there are inherent limitations to

“securing dangerous pathogens,” given the ready availability of pathogens around the world, in culture collections, laboratories, and the natural environment.

There is also a real danger that excessively intrusive or expensive security measures will discourage scientists from pursuing the research needed to treat emerging infectious diseases or to respond to a bioterrorism attack. Understanding the pathogenesis of microbes is crucial. We should not inadvertently impede progress in this work or in the development of new vaccines and medicines by imposing security measures that make science in the U.S. more difficult, costly, or burdensome while providing minimal, if any, security benefits. This is a particularly important concern because these security measures would not be imposed on scientists working anywhere else in the world.

A balanced and sensible approach to ensuring lab security would be to enact the measures called for by the Select Agent Program and Biosafety Improvement Act of 2008, which was introduced in the 110th Congress (S. 3127 and H.R. 6671). This act calls for increased biosafety oversight of high-containment laboratories, training requirements and standards, and a laboratory accident reporting system. These measures would increase biosafety and biosecurity without impeding scientific progress.

It is also important to recognize that bioscience and biotechnology are likely to serve as powerful engines of economic activity in the coming decades. Bioscience is already a global enterprise. Regulations imposed on scientific investigations should be crafted to be cost-effective, and consideration should be given to the effects such constraints might have on U.S. economic development.

Laboratory security has been a major focus internationally in cooperative threat reduction programs for former Soviet states, as well as expanded efforts in Asia, Southeast Asia, and the Middle East. The main emphasis of U.S. efforts in these countries going forward should be to expand disease surveillance to limit natural disease and detect deliberate epidemics. In addition, the U.S. should increase biosafety training for scientists and public health workers, encourage the formation of professional association chapters, encourage collaborations with U.S. scientists, and pursue joint projects on drugs and vaccines that benefit the populace of these nations and increase interactions with the U.S. scientific community. Increased surveillance and epidemiologic support would help these nations manage an outbreak—whether the outbreak occurs naturally or not.

Gigi Kwik Gronvall

PREPARING THE HEALTHCARE SYSTEM FOR CATASTROPHIC EMERGENCIES

HOSPITALS ARE THE BACKBONE of the healthcare response to mass casualty events, and they will be critically important in the response to any catastrophic health event, such as an influenza pandemic, a bioterror or nuclear attack, a large-scale natural disaster, or other emergencies described in the National Planning Scenarios.

The HHS Hospital Preparedness Program (HPP) was established in 2002 to enhance the ability of local hospitals and healthcare systems to prepare for and respond to bioterror attacks and other public health emergencies. Sixty-two entities—including all states, the District of Columbia, and the nation's 3 largest cities—participate in the HPP and have received approximately \$3 billion in HPP funding since 2002.

While there is evidence that preparedness of individual hospitals has significantly improved since the program's implementation, the nation's healthcare system still remains largely underprepared to respond to large-scale catastrophic emergencies. The U.S. healthcare system is not now capable of responding effectively to a sudden influx of patients and the resulting demand for medical resources—staff, supplies, and space—that would occur during a catastrophic event. There are a number of developments, some of them already initiated, that would greatly improve the preparedness of the system for these large-scale events.

Recommendations

► HHS and DHS should jointly develop a *national concept of operations plan for the healthcare response to truly catastrophic health events*.

In the early hours and days following the most serious and catastrophic health emergencies, such as a 10-kiloton nuclear detonation or a large-scale aerosolized anthrax attack in a major city, the response of our healthcare system will be critical to mitigating the resulting human suffering and death and overall public panic. Complex and coordinated healthcare and emergency response actions will need to be taken immediately by parties across multiple local, regional, and state jurisdictions to care for those made sick or injured by

the event, as well as the “worried well” and those who are not affected but who need care for routine and ongoing medical emergencies (eg, heart attacks, trauma, labor and delivery).

However, current public and healthcare sector emergency plans will not work during this scale of catastrophe, which would result in tens of thousands of individuals (or more) needing or seeking medical care for nonroutine illnesses (eg, acute radiation syndrome, anthrax) and potentially serious injuries.

Contributing to the complexities would be the need for an automatic response because effective incident command and control is likely to be in chaos in the first hours after such a disaster. In addition, we lack rapid diagnostics for screening victims. We have a fragmented, overwhelmed, and uncoordinated healthcare system that exists largely in the private sector. Multiple parties, including hospitals, public health departments, EMS, and emergency management agencies, are involved in healthcare response, but no one party would—or should—be in control. And critical infrastructure, such as roads and bridges, may be destroyed or blocked.

Therefore, in advance of catastrophic emergencies, a national concept of operations plan is needed that provides an overall strategy for the healthcare response and assigns clear roles and responsibilities to each participant—from the federal agencies down to local hospitals and clinics. This plan must be *national*, rather than federal, because health care is largely in the private sector. Minimally, this plan should address:

- Processes, criteria, and authorities for triggering the healthcare response to such emergencies before individual hospitals reach the point of capacity;
- Mechanisms for those in the healthcare system to achieve a level of situational awareness of the event (including the medical and public health responses) that enables them to effectively and appropriately respond in a coordinated way;
- Procedures for mass sorting, triaging, screening, and evacuating actual and potential victims;
- Systems for rapid and coordinated transportation and tracking of potentially tens of thousands (or more) of

patients to fixed or temporary facilities where health care or palliative care can be provided; and

- Means for coordinating patient care and treatment, including implementing disaster standards of care, providing palliative care, ensuring sufficient numbers of healthcare workers report to work, and coordinating volunteers.

Developing a national concept of operations for the healthcare response to a catastrophic health event will be complicated and will take a tremendous amount of political will. But until we do this, we cannot say that we have a national disaster health and medical system.

► **HHS should make healthcare coalitions the foundation of a robust national disaster health and medical system.**

One of the most significant outcomes of the Hospital Preparedness Program is the development of healthcare coalitions across the U.S. These local or regional networks of individual hospitals that collaborate on disaster preparedness and response and coordinate with public health, emergency management, and other response agencies have emerged as the foundation of a communitywide approach to health and medical disaster response. These coalitions already have proven valuable in dealing with more common medical disasters.

While these healthcare coalitions are functioning locally and regionally, they have not yet been integrated into a national network capable of coordinating health and medical response during large-scale disasters. HHS should strive to build and strengthen linkages among coalitions so that in times of national crises, coalitions can assist each other in managing the surge in demands for care, thus creating a system that is more agile and responsive. HHS is working to strengthen and link these coalitions together in important ways, and this is a critical development that should be supported and accelerated. These coalitions should play a fundamental role in our proposed national concept of operations for catastrophic health events.

► **HHS should continue to provide leadership on disaster standards of care.**

Some emergencies, such as a bioterror attack or a large natural epidemic, could overwhelm the medical capabilities of communities, regions, or even the entire country and would require drastic departures from customary healthcare practices. This shift from traditional, resource-intensive care that focuses on the individual to population-based disaster standards of care that focus on delivering the greatest good to the greatest number of patients requires the development of new clinical care standards and a process for their implementation.

Most hospitals and states have begun to address the issue

of disaster standards of care, but planning is in the early stages. While many of the issues associated with disaster standards must be addressed at the state or local level, and while some federal documents have been useful for planning, hospitals and healthcare coalitions throughout the U.S. continue to struggle with the complex issues that disaster standards raise.

HHS should continue to provide leadership to assist states in their efforts to address the many procedural, clinical, legal, regulatory, ethical, and reimbursement challenges associated with developing and implementing disaster standards of care for catastrophic emergencies. Clear national expectations and operational standards are also needed for so-called alternative care facilities (ACFs), which might be necessary in mass casualty events if hospitals are overwhelmed. HHS should take the lead for developing mechanisms to enable planners and experts across the country to share their planning approaches in support of national preparedness.

HHS will need to improve the practicality and flexibility of the process by which hospitals seek waivers or modifications of many federal requirements, such as the Emergency Medical Treatment and Labor Act (EMTALA), during public health emergencies to enable hospitals to focus their efforts on optimizing patient care. They should also recommend that legal experts develop model legislation for disaster standards of care, which states could adopt, to provide clear and comprehensive liability protections for healthcare providers who respond to catastrophic emergencies.

► **The Administration should seek to maintain or increase HPP funding for hospitals and healthcare coalitions.**

Most U.S. hospitals are private sector institutions, trying to survive financially in a highly competitive environment. Because of limited HPP funding, many hospitals contribute their own assets (eg, funding, staff time, training) to meet preparedness goals. In addition, participation in healthcare coalitions can result in additional costs. Without sustained federal funding, improvements in hospital preparedness associated with the \$3 billion investment of HPP funds are at risk, and the ability of the healthcare system to provide care to the victims of catastrophes will suffer.

The Administration should strive, at minimum, to maintain level funding for the Hospital Preparedness Program—approximately \$400 million per year—in order to maintain the current capacity for disaster medical response and to continue building local and regional coalitions. More funding will be needed to create the national disaster medical system the nation requires for biodefense and for ensuring an adequate medical response to catastrophic health events of all types.

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PRESERVING GAINS FROM PUBLIC HEALTH EMERGENCY PREPAREDNESS COOPERATIVE AGREEMENTS

FROM FY2001 to FY2008, THE federal government awarded approximately \$6 billion to support state and local preparedness activities through the Public Health Emergency Preparedness (PHEP) Cooperative Agreement grant program. This infusion of funds has enabled critical improvements in national readiness:

- A total of 150 laboratories—at least one in each state—are now capable of detecting the top biological weapons agents. Only 83 labs had this ability in 2002.
- The number of epidemiologists in public health departments working in emergency response has doubled from 115 in 2001 to 232 in 2006.
- All state health departments have staff on call 24 hours a day, 7 days a week, 365 days a year to evaluate urgent disease reports. By comparison, only 12 states had this capability in 1999.
- All 50 states and the District of Columbia now have staff trained in their roles and responsibilities during an emergency. In 1999, only 12 states had this capability.

These and other important gains are threatened by the current trend to cut federal support for preparedness activities. As states continue to struggle financially, they will be less able to meet the increasing requirements of federal public health preparedness programs.

Recommendations

- ▶ **Congress and HHS should reverse the trend of cuts to funding of the Public Health Cooperative Agreements.**

A rollback of federal funding and declines in state budgets threaten to reverse critical improvements in state and local public health preparedness. Despite increases in federal requirements for emergency preparedness, annual federal grant support for preparedness planning has decreased sig-

nificantly since 2005. The Center for Biosecurity estimates that federal support for public health preparedness decreased by 20% between FY2005 and FY2008.

At the same time, state and local governments are facing drastic shortfalls in their own budgets that will limit their ability to support preparedness programs. Following sizeable cuts in federal public health preparedness funds in 2006, states reported having to reduce staff time spent on preparedness and delay completion of preparedness plans and training staff. According to the Association of State and Territorial Health Officials (ASTHO), 27% of states have eliminated entire public health programs and a minimum of one-third of all states will lay off or cut staff in FY2009. These reductions in federal and state funding for public health emergency programs, combined with the overall economic downturn, jeopardize the many substantial and hard-won gains in readiness that the past 8 years of investment and planning have produced.

- ▶ **Given states' current economic troubles, the President should urge Congress to lift the requirement that states match federal public health preparedness funds and allow states more flexibility in hiring practices associated with emergency preparedness activities.**

The Pandemic and All-Hazards Preparedness Act (PAHPA), which reauthorized the PHEP cooperative agreement program, requires that grantees match a portion of federal funding received. States that are unable to identify funds required for the state match will lose funding. In the current economic climate, many states are unable to comply with this requirement and face the loss of many public health officials and the erosion of key emergency preparedness programs.

The Administration should also seek to eliminate requirements that prohibit states from receiving federal funds for allowing staff to work on public health programs not re-

lated to preparedness. These requirements restrict the states' ability to hire a flexible workforce and develop programs that "do more with less."

► **The Administration should ensure that federal preparedness funds are strategically awarded to areas that are at greatest risk.**

Particularly in a time of strict budgetary constraints, the nation would be better served by awarding funds to ensure that areas of greatest risk are adequately covered. The absence of risk-based funding in federal grant awards leaves the nation's most vulnerable areas with insufficient resources to prepare for threats. In 2008, Cheyenne, Wyoming, received 3 times more funds per capita for preparing for a biological attack than New York City. If funds are not available to adequately protect the whole nation, Congress and HHS should ensure that those areas that are most vulnerable are priorities for funding.

► **The Administration should work with Congress to stabilize support for federal, state, and local public health emergency preparedness activities and to reduce the administrative burdens imposed on resource-starved state and local health departments.**

States will not be able to plan strategic emergency preparedness program enhancements without some assurance from the Administration and from Congress and HHS that they will stabilize federal preparedness funding. Unpredictable fluctuations in year-to-year federal preparedness support hinder the ability of state and local health departments to hire and retain staff and to engage in multiyear program planning, resulting in huge inefficiencies. If public preparedness for catastrophic emergencies and mass casualty situations is truly a matter of national security, then preparedness programs at all levels of government should be subjected to a coherent 3- to 5-year planning and budget process, comparable to that applied to other defense expenditures.

Progress toward state and local preparedness is also slowed by the unnecessarily burdensome, uncoordinated, and repetitive administrative requirements of the panoply of federal emergency preparedness grant programs. DHS, CDC, and HHS all administer separate grant programs that support preparedness programs at the state and local levels; however, the submission cycles and reporting requirements of these grants are not coordinated or streamlined. Consequently, precious state and local public health resources are spent on administrative paperwork resulting

from these separate federal preparedness funding streams. A common format and timeline for submitting these grants would alleviate a great deal of the strain induced by the requirements of the individual grants. Additionally, federal agencies could reduce the unnecessary administrative burden of these grants by synchronizing the funding and reporting cycles of preparedness grants in coordination with state fiscal years.

► **The Administration and Congress should create provisions to ensure that public health agencies are able to recruit and retain adequately trained personnel.**

The nation's ability to respond to health emergencies hinges on maintaining a competent public health workforce. But the workforce in state public health agencies is graying at a higher rate than the rest of the American workforce. According to a recent survey, nearly half of all states have 25% or more of their public health workforce eligible to retire in the next 5 years. Despite public health associations' best efforts to recruit and train new workers, state budget deficits and declining federal support for public health preparedness programs make it difficult for public health agencies to hire new personnel. Unless this trend is reversed, state and local agencies will be unable to recruit the talented workers needed to replace a graying public health workforce.

There is evidence that interest in public health careers is growing. Between 1995 and 2005, the number of students enrolled in accredited schools of public health increased 35% (in the same period, medical school applications decreased by 20%). The country should try to make use of this appetite for public service. The Administration should press Congress to appropriate funds to implement the public health workforce loan repayment program authorized by the 2006 Pandemic and All-Hazards Preparedness Act. This repayment-for-service program will encourage trained public health professionals to pursue employment at federal, state, or local public health agencies.

The Administration should take steps to enable mid-career professionals to spend time in federal government posts—for example, by offering 1- to 3-year Intergovernmental Personnel Act assignments (IPAs). The federal agencies should also move immediately to increase the speed and transparency of federal hiring practices, allowing applicants with appropriate technical and professional credentials to serve.

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DEVELOPING A NATIONAL BIOSURVEILLANCE PROGRAM

HOMELAND SECURITY PRESIDENTIAL DIRECTIVE 21 (HSPD-21) and other policies have underscored the strategic importance of developing and maintaining a national biosurveillance program in order to maintain situational awareness during catastrophic health events. The federal government has made considerable investments in deploying biosurveillance systems across the country, but it has done so without a clear overarching federal strategy for designing or testing these systems or a strategy for funding, staffing, or maintaining them. The absence of clear national biosurveillance objectives and implementation plans has contributed to several problems:

- The creation of hundreds of separate surveillance programs that serve a range of purposes, many of which are duplicative or have overlapping missions, and most of which are not interoperable.
- An inability for agencies or programs to assess or prioritize information from existing systems or to pursue the addition of new data streams. Agencies are struggling to figure out whether it is better to engage in a “more data, faster is better” approach or whether it would be more effective to pursue fewer, more meaningful data streams.
- A lack of understanding of the specific “mission space” and objectives of state and federal agencies that are involved in biosurveillance.

Recommendations

► **It is critical that the ongoing internal and external reviews of federal biosurveillance programs lead to a more systems-based approach to implementation and continuous improvement.**

Both the National Academy of Sciences (NAS) and the Centers for Disease Control and Prevention (CDC) have assembled advisory committees to review U.S. biosurveillance activities. The NAS review was mandated by Congress; the CDC Committee was mandated by HSPD-21.

U.S. biosurveillance strategy needs to define the missions, goals, and priorities of federal investments in biosur-

veillance activities, and the government must periodically assess the effectiveness of different biosurveillance activities and systems in serving these goals and priorities. Key elements of this assessment should be:

- Clear performance objectives for biosurveillance systems must be devised. There is no straightforward consensus on what specific information or activities are needed to detect and manage catastrophic public health events at state and federal levels, in part because the information required differs from one emergency to the next. Ways of judging the comparative effectiveness of different surveillance systems should also be developed.
- There is a need for a strategic plan to achieve some degree of interoperability among different surveillance systems or at least interpretive transparency of these different systems where needed.
- The government must create a prioritized approach (including budgetary needs) for building and maintaining surveillance systems over time.

One approach to assessing the effectiveness of existing surveillance systems and to helping identify what information will be most critical during mass casualty events would be to use rigorous and comprehensive after-action reports of past events and exercises. Reports from these events should be shared across agencies and state health departments. If events reveal gaps in existing biosurveillance capacity, federal agencies should work together to figure out how necessary information should be obtained to avoid developing duplicative programs.

► **The Office of Management and Budget should conduct a cross-agency analysis of federal budget outlays for biosurveillance programs to prioritize the funding of critical programs and to eliminate ineffective or redundant programs.**

To date, there have been no reliable analyses of how much the federal government has invested in biosurveillance nor has there been a comprehensive accounting of all the federal

programs that pertain to biosurveillance. Without such a review, it is difficult to assess whether critical programs are adequately funded or to eliminate ineffective or redundant activities. To that end, OMB should undertake a cross-agency review of biosurveillance programs in the federal government. The processes for establishing biosurveillance goals and priorities and for evaluating programs should be as open and objective as is feasible and consistent with national security.

► **As a central goal of its effort to improve health information technology across the nation, HHS should support the development of robust, interoperable linkages between public health and healthcare delivery institutions such as hospitals at the state and local levels. These connections should serve as the foundation of the national biosurveillance enterprise.**

State and local surveillance programs are the foundation for an integrated national biosurveillance system. The federal government's capacity to detect and maintain situational awareness during catastrophic events depends on the ability of state and local agencies (particularly health departments) to build and maintain robust and flexible linkages to the healthcare system. However, this bottom-up strategy is threatened by the variability in state and local financial resources. The significant state budget deficits being caused by the economic downturn are already making it difficult for agencies to maintain information systems and analytical staff.

The CDC public health emergency preparedness cooperative agreements have enabled state and local health departments to begin to develop basic biosurveillance capabilities. While these investments have been an important first step, the level of federal and state funding for biosurveillance appropriated to date is not commensurate with the strategic importance of these systems. As the nation builds a national framework for clinical electronic health records—the Health Information Exchange architecture—federal agencies should not lose the opportunity to develop critical connections between health care and public health. A portion of the federal funds being spent on the Health Information Exchange should be used to build and maintain digital connections between public health agencies and healthcare entities. To support these efforts, HHS must provide these funds on a long-term and continuous basis.

While continued federal funding is critical to building and sustaining a national biosurveillance enterprise, some

biosurveillance systems should be reevaluated. In the past few years, federal and state governments have used federal biosurveillance funds to develop environmental detection (such as BioWatch) and/or syndromic surveillance systems that are intended to provide an early warning of a catastrophic event. However, there are few rigorous assessments of the efficacy or cost-effectiveness of these types of systems. In particular, the extent to which these systems provide actionable data is not clear. There should be clear and objective evaluation of existing environmental detection and syndromic surveillance systems to determine if these systems warrant continued investment.

► **The federal government should invest in efforts to develop rapid, point-of-care diagnostic tests that can be used to quickly identify people who are ill and to help isolate contagious people from those who are well.**

Rapid access to accurate and reliable diagnostic data will be of the highest strategic importance in a catastrophic health event. Clinical laboratory data is very specific and reliable—much more so than syndromic data or physicians' clinical assessments. Technologies to develop rapid, reliable, and cheap diagnostic tests exist, but they have not been developed because of market failures. The Biomedical Research and Development Authority (BARDA) is authorized to develop and purchase the diagnostic tools that will be necessary to manage public health emergencies, but appropriations needed to pursue this priority have not been forthcoming.

► **The federal government, along with the states, should develop a cadre of highly skilled and competent analysts to build and maintain biosurveillance systems at the federal, state, and local levels.**

State budget deficits and layoffs threaten to exacerbate existing shortages in skilled personnel to manage critical public health programs. The federal government must make a sustained and committed effort to ensure that adequate funds are available to hire and retain competent personnel to run biosurveillance programs at all levels of government. To attract the highly skilled, highly sought-after technical experts who will be needed to manage biosurveillance systems, the federal government should consider offering tuition-for-service programs and short-term Intergovernmental Personnel Act assignments (IPAs).

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EXPANDING THE PUBLIC'S ROLE IN HEALTH EMERGENCY POLICY

THE INCOMING FEDERAL LEADERSHIP can enhance the country's resilience to catastrophic health events by enabling individuals, families, and community groups to engage in a broad range of civic contributions, including individual self-protection, collective volunteer action, and communitywide deliberation of health emergency management policy.

National policy has traditionally defined the role of citizens in public health preparedness as assembling an emergency stockpile and listening to the radio or television for official instructions. But in practice, U.S. residents and civic groups have played a far greater role in disasters and epidemics. In an emergency, family, friends, coworkers, neighbors, and bystanders often conduct search and rescue and provide medical aid before police, fire, and other officials arrive on the scene. During major outbreaks of smallpox, polio, and HIV/AIDS, volunteers have helped run mass vaccination clinics and nurse homebound patients; they have supported the sick and their families with basics like grocery shopping and childcare; and they have participated in policy decisions about disease prevention, care delivery, and drug development.

Recommendations

► The Administration should work with Congress to fund public preparedness and community resilience at levels commensurate with their official status as core features of public health security.

Both the executive and legislative branches of the U.S. government have said that members of the community have key responsibilities in public health preparedness, yet federal funding does not reflect this position. The 2007 Homeland Security Presidential Directive 21, National Strategy for Public Health and Medical Preparedness (HSPD-21), named "community resilience" as one of the "four most critical components of public health and medical preparedness" along with biosurveillance, countermeasure distribution, and mass casualty care. The bipartisan-supported Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA, P.L. 109-417) identified "public preparedness" as an "essential public health security capabilit[y]."

But public health preparedness dollars do not support the public's active role in health emergencies in any substantial way.

To engage the U.S. public more fully in public health preparedness, the Administration should seek to have Congress:

- Restore the Public Health Emergency Preparedness (PHEP) grant funding to its original levels. Community members require strong health departments with which to partner, and federal monies have been essential in building the core preparedness and response capacities of state and local health departments.
- Augment baseline PHEP funds with additional monies that would enable state and local health agencies to increase their public involvement activity, most notably in building partnerships with grassroots groups and local businesses and in engaging the public in health emergency policy decisions. Health agencies require dedicated staff and administrative capacity to carry out these additional labor- and time-intensive activities, and community- and faith-based organizations with limited resources need incentives to join the health emergency planning table.

► CDC should help augment state and local health departments' capacity to build partnerships with community- and faith-based organizations and local businesses.

Initial PHEP investments in risk communication have largely fostered one-way flows of mass-mediated information to the public; the next step is to build two-way channels with grassroots leaders. Working alongside health authorities, community- and faith-based organizations and local businesses can reach out to vulnerable populations, disseminate meaningful emergency health messages, and help plan the mass distribution of drugs and vaccines.

Preparedness grants to state and local health departments identify "risk communication and health information dissemination" as one of 7 priority areas. Many health agencies have used this funding stream to train designated spokespersons and hire public information officers. Simi-

larly, CDC should designate “community resilience partnerships” as one of the funded PHEP activities and provide incentives to health departments to hire the necessary personnel to interact with grassroots leaders over time. Partnerships will be unable to flourish without dedicated staff to nurture relationships.

► **CDC should enable community- and faith-based organizations, especially those who represent vulnerable populations, to collaborate more easily with health and disaster agencies.**

Neighborhood associations, faith-based communities, trade groups, fraternal organizations, ethnic centers, social service nonprofits, and other civic-minded organizations can mobilize their networks for public health preparedness aims. These diverse groups can develop their own continuity plans, represent their constituents in official health emergency planning, tap into pre-event public education and crisis communication campaigns, provide mutual aid in an emergency, and offer logistical support to professional responders.

Just as health departments must enhance their capacity to interact with grassroots leaders, so too must community- and faith-based organizations be enabled to work more closely with public health and disaster agencies. Health departments must receive sufficient funds, grant-making flexibility, and direction to allocate a meaningful portion of the PHEP dollars to grassroots organizations. Nonprofits may be unable to join the health emergency planning table if it means diverting their limited resources to an additional mission. Priority recipients of PHEP support should be nonprofit groups rooted in and representative of minority communities where social networks, cultural practices, and special needs are not well understood by mainstream organizations.

► **The Administration should urge Congress to authorize legal protections for nonprofit and business entities that act in good faith during a public health emergency.**

Nonprofit and business entities have expressed reluctance to volunteer their resources in emergency response and recovery efforts if the organization can be held liable for its good faith actions. Some state legislatures have passed legislation that provides Good Samaritan liability protection to entities, but entity protection is still less common than protections for individual volunteers. Congress should legislate a uniform federal approach to this issue and more quickly achieve a national state of legal preparedness.

Another inhibition to nonprofits and businesses participating in community public health preparedness efforts is concern over the lack of “workers’ compensation” or similar injury/illness benefits for the individual volunteers de-

ployed. This is especially a concern in the case of communicable diseases. Legal protections, thus, should address both liability and workers’ compensation concerns.

► **CDC should equip more state and local health agencies with the skills to engage the public in health emergency management policy decisions.**

Efforts to incorporate citizen input into public health preparedness policy decisions—that is, “community engagement”—have occurred but only on an ad hoc, experimental basis; these efforts have not yet been institutionalized at the state and local levels. For example, in 2005 federal health authorities piloted public deliberations among citizens-at-large and national stakeholders about the best early use of limited vaccine in an influenza pandemic and, in 2006, about potential communitywide control measures to slow the spread of flu. In September 2008, CDC awarded grants to 6 state and local health agencies for demonstration projects that engage residents in the decision-making process for pandemic flu preparedness.

To encourage more state and local health agencies to replicate these innovations, CDC should identify community engagement as a priority objective in PHEP guidance. In addition, CDC should provide technical guidance and promote peer-to-peer mentoring between health departments that are more novice and those that are expert in public involvement techniques. The benefits of community engagement include fostering greater trust between the public and officials, incorporating local knowledge that ultimately improves plans, having policy decisions reflect public views and preferences, and building up a political constituency that ensures follow-through on policy decisions.

► **The Administration should increase volunteer opportunities for Americans to protect the health, safety, and security of their hometowns.**

In the wake of the September 11 attacks and the resulting groundswell of volunteerism, the federal government established the Citizen Corps (CC). But despite the initial fanfare, support for this initiative has remained modest. The Medical Reserve Corps (MRC) program in HHS and the Community Emergency Response Teams (CERT) program under DHS/FEMA are 2 of the CC partner programs that have strongly been engaged in hometown security. MRC units are made up of volunteer physicians, nurses, epidemiologists, veterinarians, and other health professionals, as well as non-medically trained personnel. They augment an area’s response to a health emergency and promote improvement of the public’s health on a routine basis through activities such as health fairs, immunization campaigns, and disease screenings. CERT members learn about

disaster preparedness; train in basic skills such as fire safety, first aid, and search and rescue; and stand ready to act in their locality.

To create more opportunities for U.S. residents to protect the health, safety, and security of their hometowns, the Administration should urge Congress to pass authorizing legislation for the Citizen Corps and to appropriate sufficient funds to enable more states and localities to set up and maintain fully functional Citizen Corps Councils (CCCs), MRC units, and CERT teams. Mature CCCs depend on dedicated coordinators to help engage the public in disaster management policy and to coordinate disaster-related volunteer programs.

If public preparedness for a health emergency is ever to become something more than a motto, then the icon of

the stockpiled basement needs to be demoted. In its place can be the town hall meeting or the neighborhood association blog where top health emergency questions are debated, such as who will care for large numbers of sick people when hospitals are overburdened. Another image is a council of nonprofit and business leaders who work alongside local authorities to plan the mass distribution of antibiotics or emergency health information. Federal leadership and financial support can help realize these and other meaningful visions of public preparedness throughout the U.S.

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DEVELOPING MEDICAL COUNTERMEASURES FOR BIODEFENSE

HHS IS RESPONSIBLE FOR researching, developing, manufacturing, and stockpiling the medicines, vaccines, and other medical products, also known as medical countermeasures (MCMs), that will be needed to care for the sick and protect the healthy in the wake of bioterrorist attacks (as well as nuclear, radiation, and chemical attacks) against the U.S. population. The nation currently lacks MCMs against many biological threats. Other MCMs exist only in limited quantities. For example, there are no FDA-approved vaccines or therapeutics to counter an Ebola infection, and no FDA-approved, rapid, point-of-care diagnostics exist for any of the biothreat agents of greatest concern. These products do not have traditional commercial markets, so private-sector biotech and pharmaceutical companies have little incentive to develop them without significant government support. HHS has thus far determined 8 MCMs are required to defend Americans against biological attacks, with at least 3 more required to defend against chemical, radiological, and nuclear attacks.

The transformation of a promising drug candidate into a licensed product typically takes 10 or more years from basic research to approval by the FDA, at a cost of hundreds of millions of dollars. These costs and timelines are driven by the uncertainties and risks associated with drug development. It is estimated that of every 5,000 “candidate” drugs that look promising on the lab bench, only 5 enter clinical trials, and only 1 of those achieves FDA licensure.

While funds have been provided to HHS for MCM development, they have been far from sufficient given the costs of drug development and the number of MCMs needed. NIH has received approximately \$1.6 billion per year since FY2004. BARDA was created by Congress in December of 2006 (Pub. L. No. 109-417) and received \$201 million in FY2007–FY2008. For FY2009, BARDA received \$275 million, which was transferred to it from the BioShield Special Reserve Fund. The BioShield program was created by law in 2004 (Pub. L. No. 108-276). Its Special Reserve Fund (SRF) for procurement has a \$5.6 billion multiyear appropriation (FY2004 to FY2013); to date \$1.9 billion has been spent or obligated. The Department of Defense (DoD) also has an MCM program; in FY2008, the

“medical systems” component of this program for research, development, and procurement of new medicines and vaccines was \$341.9 million.

The enterprise dedicated to developing new MCMs has the potential to improve national security as well as to be an engine of innovation for battling all infectious disease threats. Since 2001, HHS has worked to develop effective programs, hire staff with relevant expertise, and build partnerships with the private-sector developers of medical products. HHS is now in a position to successfully move forward on its mission to catalyze research and develop and manufacture MCMs for the civilian population. But this vision will remain unfulfilled if the enterprise is not appropriately funded, staffed, and empowered by effective leadership from the White House.

Recommendations

► **The Administration should ensure that funding for basic science research in biodefense remains steady and that this work is linked to an overall strategy and to biodefense needs and requirements.**

Basic science funding for biodefense has led to fundamental discoveries that lay the foundation for early development efforts leading to vaccines, medicines, and diagnostic technologies. This work also focuses on critical scientific challenges that underpin these efforts, such as adjuvant science, immunology, and microbial pathogenesis. As an example of the value of the basic science biodefense effort, the NIH Regional Centers of Excellence have been highly productive, as measured by the number of new faculty drawn into this field, the quality of the collaborations, the papers published, and the patents filed. This basic science research enterprise should continue to be supported in the new Administration. To the maximum extent possible, the basic science efforts for biodefense should be linked to the other elements of the countermeasure development and procurement process. The more effectively these efforts can be connected, the more efficient the government management of the enterprise, and the

more transparent and clear the process for the private sector companies who are developing new biodefense medicines and vaccines.

► **The President should make full funding for BARDA a top priority.**

Since its creation in December 2006, BARDA has received approximately \$100 million per year. The failure to fund BARDA adequately means that the investments made in NIH to advance basic science cannot be translated into effective medicines or vaccines, which means that there are no products to purchase for the Strategic National Stockpile using BioShield funds. BARDA was designed to provide “advanced development” support for MCMs that have no commercial market. Without federal support for this crucial phase of development, private sector biopharma companies are unlikely to participate in biodefense and the country will be without MCMs. HHS’s successful pandemic influenza MCM development program illustrates that BARDA can successfully manage ambitious advanced development projects. However, BARDA does not have sufficient funding to accomplish its mission for CBRN MCM development. The Center for Biosecurity estimated, based on publicly available industry data, that to have a 90% chance of successfully developing MCMs for the 8 biodefense requirements already determined by HHS, BARDA would need \$14 billion through FY2015. The Center has recommended \$1.7 billion for FY2010.

► **The President should direct HHS to provide funding and personnel to foster collaborative public-private partnerships to establish paths to regulatory approval for biodefense MCMs.**

Currently, there is not a clear regulatory path to FDA approval of biodefense MCMs, since most cannot ethically be tested for efficacy in humans. The FDA’s Animal Efficacy Rule establishes a pathway for biodefense MCMs to be proven effective using validated animal models; however, for many biodefense diseases of concern, animal models have yet to be developed and validated.

Public-private partnerships among government, industry, and academia could focus on sharing animal models and precompetitive model validation data and on encouraging dialogue between developers and regulators. In a related issue, it is unclear what standards for safety and efficacy will make products that are in late-stage development, but not yet FDA approved, eligible for use in a crisis via an Emergency Use Authorization (EUA). These regulatory risks are major barriers to private sector engagement in MCM development.

► **The President should request funding and provide leadership for a partnership between MCM developers and HHS, DoD, and other federal agencies to develop one or more facilities that aggregate expertise and infrastructure for MCM advanced development, manufacturing, and regulatory affairs. This partnership would work to improve all MCM development—lowering risk, reducing costs, and accelerating timelines.**

Specialized technical expertise (eg, medicinal chemistry, analytics development, bioprocess engineering, animal study development) is needed in each stage of MCM development for it to be successful. However, much of this expertise is distributed throughout industry and is frequently treated as proprietary. To meet the government’s MCM development requirements, this expertise must coalesce and become available to a wider array of the partners in the MCM development enterprise. This is especially true of process development, manufacturing skills, and regulatory expertise. Much of this know-how resides in “big pharma,” which currently does not participate in biodefense. Government-sponsored public-private partnerships, combined with dedicated facilities or centers of excellence that concentrate the necessary combination of development expertise, should be initiated to support biodefense MCM development requirements. These partnerships and innovations can and should be used to catalyze medicine and vaccine development for a range of naturally occurring infectious disease threats as well.

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