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Special Feature: Health Security Memos to the New Administration and Congress

Protecting the Nation from Health Security Threats

Events in the United States and internationally have shown the kinds of great stakes and consequences that often follow epidemics and disasters. Consider the series of health security shocks since 2001: National fear during the anthrax letters events, with impact on all 3 branches of the US government. The respiratory transmissible SARS and MERS viruses spreading via airplanes and hospitals, sometimes by super-spreading individual patients. Human cases of H5N1 bird flu with a case fatality rate of 50%. The sudden emergence and global spread of 2009 H1N1. The congenital malformations following Zika infections—the first mosquito-borne illness to cause such malformations. The terrible mortality and wide spread of Ebola across multiple countries in West Africa, with imposition of large-scale quarantines and costly economic disruptions to trade and travel. The widespread disabling of the healthcare system during major US hurricanes. The use of chemical weapons in war in the Middle East, breaking years of international taboo against it. Discovery of smallpox in an insecure box in a US government lab. The radiation risks and uncertainties over large areas following the Fukushima tsunami and nuclear power plant accident. High-containment laboratory accidents involving important live pathogens.

Beyond these events, there are other important potential threats that could cause great harm and test our systems of health preparedness in the United States and internationally, including large earthquakes, substantial terrorist attacks, and nation state or terrorist use of biological, chemical, radiological, or nuclear weapons—events that could have the potential for great loss of life. In the realm of synthetic biology, the possibility of generating novel laboratory strains that have both high lethality and are readily transmissible is an important new challenge that the world needs to manage.

These are problems that have the potential to cause sickness, mortality, and disruption on a large scale. But the consequences are not limited to health. Outbreaks and other disasters can come with the potential to have an impact on economies by shutting down commerce, or by causing widespread anxiety that affects the public in ways that have ripple effects on work and spending. Some outbreaks have caused governments to make bad choices to quarantine people in ways that did not end epidemics but that did cause loss of trust in government. Some of these events have reduced confidence in and credibility of political leaders.

Health security is the collective effort to prevent, mitigate, and recover from the health consequences of these kinds of epidemics, disasters, and catastrophes. In many of these events, major initial impacts are related to health and loss of life. But when health consequences of this nature and potential scale occur, or are legitimately feared, then economic, governance, political, and security consequences can quickly follow.

The US government—working with partners at the state and local levels, the NGO community, the private sector, and the public—has done an enormous amount in the past 15 years to prepare for these kinds of events at home and, to a lesser extent, to help build strength abroad in ways that protect other countries and our own. But even with all this work, it's clear that our preparedness for these kinds of problems is often not substantial enough for the big challenges we face. In many cases, US programs are too small,

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the funding is too jerry-rigged, or we haven't made the necessary investment in technology or in people.

In the past, prominent government leaders have asked, "Isn't the work of preparing for large-scale health emergencies completed yet?" The answer is that health security is not something that gets completed. Just like national security is not something that is ever fully completed. Long-standing threats continue to persist and new challenges emerge, so it is crucial to remain prepared and keep looking ahead. Talent must be recruited, and new systems have to be built and evolve. And if we don't continue to support these efforts, the infrastructure behind them will degrade and preparedness will suffer.

Even for the systems that have been built and are strong, there are limits. The United States has not confronted truly large-scale catastrophes, as might for example happen with a novel pandemic disease. It has been hard enough to build systems that address modest-sized epidemics and disasters.

One of the primary functions of government is to protect its people from the greatest dangers they might face. Larger-scale biological catastrophes should be on that list of potential greatest dangers, so we need some aspect of our national preparedness effort to be working to diminish the likelihood of those kinds of events and to lessen the consequences of potentially globally stunning events. As part of that work, we need a better understanding of the pathogens and conditions that could cause new biological catastrophes. At a basic level, we also need a way of communicating and planning around these events, with language that is clear and doesn't lead to people becoming resigned to suffering the consequences of these events or dismissing the possibility of their happening.

The transition to a new Administration and Congress is a critical time to take stock. It is a time to make adjustments and consider ways of making programs more effective and efficient. But most important, the beginning of a new administration presents a unique opportunity to institutionally and politically emphasize new (or as yet unachieved) goals that will set the direction for programs and agencies.

Our colleagues at the Center for Health Security have written a series of commentaries that follow this one that provide facts and assessments regarding what has been established in key realms of health security and what needs to be done now. We highlight some of these recommendations below and give our thoughts on ambitious goals that could, if embraced by the new Administration, significantly advance our national ability to save lives, economies, and societies when faced with serious health security threats. Some of these goals have been aspired to for a long time, but there has not been the kind of national commitment to fully achieve them. The new Administration and Congress could collectively realize all or part of this vision and transform health security in the United States.

- **The United States needs to improve the ability to develop new medical therapies and vaccines to cope with biological threats the country may face.**

The United States should have, but currently does not have, the capacity to develop a new vaccine or medicine quickly for any novel biological threat that we face from either nature or a deliberate attack. Our nation has invested in and built impressive systems for research and development of medical countermeasures for biological threats, antimicrobial resistance, pandemic flu, and emerging epidemics. It has a program that draws on the talents and science of NIH, ASPR/BARDA, FDA, CDC, and DoD (also known as the Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE), working closely with biopharma companies. The United States and other countries have depended on our systems during past events. For example, the US government and its biopharma partners led a global development effort for medicines and vaccines after anthrax 2001, for H5N1 bird flu, for 2009 H1N1, for Ebola, and now for Zika, as only a partial list.

Even with these successes, the drug and vaccine development process has mostly taken too long to make a difference during the most important period of a new outbreak. For instance, it is likely to take at least 6 months after the discovery of a new flu pandemic for this system to produce an effective vaccine. And flu is the best case. For many other new threats, it can take a decade or longer to develop new medicines and vaccines. We agree with the recent President's Council of Advisors on Science and Technology report, which called for the US government to develop the national capacity to make a new vaccine or medicine for any new biological threat within 6 months. To get there, this goal must be made explicit, technology investments will be required, and progress toward it should be tracked.

In the meantime, as the government works toward that longer-term goal, the programs of government that develop medical countermeasures in partnership with industry need to be supported and strengthened, and talented people need to be recruited and retained to run them. Incentives for participation by industry must be effective, and the structure of these incentives will vary depending on the threat and whether there are markets beyond the US government for the products being sought.

- **The United States must have a healthcare system that can more efficiently surge to provide care for the ill and injured during epidemics and catastrophes.**

While our country's preparedness programs have successfully readied our healthcare system to respond well during community-level events, we still have a way to go to truly build the healthcare system's capacity to manage highly contagious patients during an epidemic and to manage patients following major disasters. In the years since 9/11, there have been a range of important efforts to improve the

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capacity of hospitals to respond to disasters, including the ASPR Hospital Preparedness Program, the National Disaster Medical System, CDC's Public Health Emergency Preparedness Program, and the Medical Reserve Corps. Taken together, these programs have helped to create a cadre of professionals dedicated to healthcare system preparedness for disasters. What used to be largely an after-hours volunteer-only avocation is now a serious preparedness community. As a result of this and of equipment, technology, and infrastructure improvements, many hospitals now have built the capacity to deal with disasters in their communities, and the programs have been valuable in a range of natural disasters.

However, there are important challenges. There is limited capacity to manage highly contagious patients. The response to Ebola cases showed how much advanced training and dedicated staff matter to that kind of response. Specialized infectious disease hospitals have been designated in the aftermath of Ebola, but they will need continued support to maintain that capability. There are also limits to the number of medical or burn casualties that can be cared for in a city or a region. The number varies around the country, but because of financial constraints on hospitals, most preparedness efforts are intended to be able to cope with only small disasters (eg, crashes, building fires, storms) and would not be capable of handling larger epidemics or catastrophes.

Many components of the healthcare system outside of hospitals would be critical to responding to larger events, but they have typically not been included or supported in this work. More of the community will be needed to be engaged to make progress in this work. A new CMS rule may also help expand the system of preparedness beyond hospitals themselves, but it is not clear where the funding will come from to do the work. US government funding for healthcare system preparedness has been cut by more than half from 2002 levels for unclear reasons, stymieing progress. In order to have a healthcare system that can handle a larger number of highly contagious patients or mass medical casualties, we need to build and fund these kinds of efforts.

- **The United States needs a public health system that has the expertise and technology to give us earlier warning of outbreaks and disasters and can lead our efforts to deal with them.**

In order to serve as America's first line of health defense against outbreaks, disasters, or the use of biological, chemical, or nuclear weapons, the US public health system is in critical need of 3 basic things: more people, a better funding structure, and modern technology. Unlike the very challenging objective of developing a new medical countermeasure within 6 months of a novel outbreak, it would be fairly straightforward to hire more people and invest in modern technology for our public health departments. But the reduction of funding for public health over the past several years has put such basic requirements out of reach and has weakened our ability to get out in front of outbreaks to limit their impact. The National Health Security Preparedness Index assesses state readiness over a range of capacities, and the most recent scores showed an average state ranking of 6.7 out of 10, a grade that shows that, while there is capacity in the system, there is a long way to go.

For any epidemic or large event involving health consequences, public health leaders and the systems and organizations they lead are a major component of the response. A professional public health preparedness community has been built in the past 15 years, led nationally by the CDC and led locally by state and local health departments. Public health agencies provide top-level scientific analysis and expertise on infectious diseases and epidemics; surveillance programs for early warning of new outbreaks; laboratories for diagnosis and research and the safety programs that go with them; public communication; networks to keep health officials informed; medicine stockpiles; and programs that help build response capacity in communities. But there has been downward funding pressure on the system: Health departments have lost substantial federal resources over the years, and along with that many people. The responses to Ebola and Zika were intensive and resource-draining for many. We seem to fund public health only after an emergency happens, and even then the funding is tied specifically to the emergency at hand, thus restricting the ability of public health departments to build broader capacity over time.

On the other hand, some good news for the country is that there are high numbers of young people pursuing undergraduate and graduate careers in public health. We need more programs and resources to get this rising talent into places where they are needed most. We also should make sure public health has current technologies at its fingertips. Public health particularly needs both more advanced diagnostics and functional IT systems that can connect it to medical providers. In many places, public health lags far behind the private sector in technology investment because budgets have not allowed for it. It will also be important for us to systematically study and learn from our increasingly frequent response to outbreaks nationally and internationally. Not only do we need scientific research to understand the pathogens and diseases, but we need the systems analysis and operations research to study and understand whether our organizations and approaches are working and the extent to which they will scale in more serious biological crises in the future.

- **The United States should bolster international efforts to protect the nation by stopping infectious disease at its source and working to prevent bio, chem, and nuclear proliferation.**

One clear lesson from epidemic response in the past 15 years has been that we need to work internationally to help contain outbreaks that develop elsewhere. Not only is it the right thing to do because we have the expertise that can help, it is often the only thing that will prevent the spread of

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problems to the United States. The International Health Regulations (IHR) have been of great benefit because they have made it an international norm and expectation that countries will prepare themselves to discover and respond to outbreaks, but most countries are not able to meet the IHR standards without substantial technical or other resource support. We all witnessed the complexity and fragility of the international response to Ebola. The WHO reforms for epidemic response coming out of this crisis are therefore of high-stakes importance. So too are the steps that countries take on their own to prepare to help with emergency international epidemic response. In the United States, for example, we need a stronger and faster way to deploy doctors and nurses to help prevent the medical response from collapsing into chaos in extraordinary epidemics.

A development that has been transforming international preparations for globally important epidemics has been the Global Health Security Agenda, a strategy and program that enlists the talent, resources, and commitment of a large group of nations that have resolved to help build epidemic response in countries which are not prepared yet to identify or stop new outbreaks. Recently, countries have undergone first-ever external evaluations of their preparedness efforts, with the hope that these efforts will spur more change, bring in expertise where needed, and shine an international light on the need for national health security and preparedness.

The United States should continue to support and help build the GHSA, because it is in the strong interest of US health and national security to ensure that other countries have the capacity to stop outbreaks before they spread internationally. Since the start of the GHSA, countries are now sharing crucial epidemic planning and response information with each other through transparent external evaluations for the first time. In addition, the GHSA shares the burden for helping to improve countries' epidemic response capacities, distributing it broadly among nations. An important additional step would be to establish an international index of capacity that would help independently assess progress over time.

In the realm of deliberate biological threats, the BWC continues to be a crucial norm against the development or use of biological weapons. Especially in a time when countries have violated the chemical weapons norm, maintaining the norm against biological weapons is critical. Efforts to maintain or restore global norms against development and use of chemical and nuclear weapons are also now vitally important.

- **The United States needs to anticipate and apply powerful new biotechnologies that are coming online in order to make the most of them and to manage consequences should they go wrong.**

The United States should maintain its international position and leadership in the biological sciences, both because of the many associated scientific and economic benefits but also because of the need to help shape the emerging ethical, safety, and security rules of the road. It would be hard to miss the biotechnology revolution going on around us. Biotech is a powerful global engine for science, medicine, agriculture, and the economy writ large. CRISPR/Cas is only one of the most visible tools emerging—experts in bioengineering say we should expect transformative tools like it to emerge again and again, suddenly. Countries around the world are making big investments. The gene editing/genome engineering market alone will be worth $5.5 billion in 2021.

The US government should quite deliberately and strategically be scanning the horizon for new technologies and industrial approaches that we can use to help prevent and prepare ourselves for biological threats of the future. Changes to automation, industrialization, informatics, engineering, manufacturing, and more will bring incredible opportunities to transform the way we deal with biological threats.

We also need to anticipate and react wisely to the new challenges, and even dangers, that biotechnology will bring. One example of the kind of challenge that the United States—and the international community—need to address is how to manage research that can result in the creation of novel, highly lethal, highly transmissible viruses that do not exist in nature. The concern is that such work increases the chances that a laboratory accident or security breach could result in exposure of laboratorians or the public to a novel and highly pathogenic virus. This is an issue that became public over the past few years and has resulted in a moratorium on such work. In our view, there is now visible a circumscribed area of experimental work that poses extraordinary pandemic dangers and so should require extraordinary justification if it is to be pursued. The US government is now working through its approach to and policy on these experiments, and the new Administration should attend to this process carefully. Other unexpected developments in biological science will continue to occur and require the attention of the US and other governments. Creating biosafety norms internationally for experiments that have the potential to cause great harm following accidental or deliberate spread should be an international science priority.

- **The United States must provide the leadership and organization to advance health security.**

Taken together, the recommendations here and in the commentaries that follow are really about building a more robust health security infrastructure in the United States. This work will immeasurably help the United States to stay ahead of the preparedness curve and to minimize the economic, human health, and societal impacts of outbreaks and disasters that will surely challenge us in the future. Given how broadly distributed health security responsibilities are in the US government, a senior White

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House leader and staff should be given responsibility for top-level leadership of health security efforts across the government.

Beyond the White House, there need to be leaders in the federal agencies and Congress who are concerned about these challenges, highly informed about developments in infectious diseases and bioscience, and committed to addressing them. Our Center's Emerging Leaders in Biosecurity Fellowship program is intended, in part, to help foster the generation of new leaders who will rise into these positions. Other efforts will be vital to build, educate, and empower this community nationally and internationally, since so much of this work has elements that cross borders.

With strong commitment, focus, and resources, the goals we describe above are within reach. We look forward to working with Congress, the new Administration, and other nongovernment partners to help catalyze and support this vital work.

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Healthcare Preparedness: Saving Lives

Preparing our hospitals and other healthcare facilities for disasters is a national security priority. Disasters occur nearly every day in the United States, and the frequency is increasing. This includes such diverse events as storms, droughts, wildfires, floods, earthquakes, chemical and industrial accidents, burns, mass shootings and bombings, and epidemics. All sickened or injured people require a well-prepared public health and healthcare system. The number of people killed by disasters depends not only on the severity of the event itself but also on our ability to respond effectively and treat the ill or injured. This is true of all disasters, whether they are natural disasters like earthquakes and hurricanes or manmade disasters like terrorism. It is also true of infectious disease epidemics, whether of natural or manmade origin.

Healthcare Preparedness Reduces Risk

In theoretical terms, Risk = Threat × Vulnerability × Consequence. Thus, even if we are not successful in reducing the threat of disasters or our vulnerability to them, we can reduce our nation's risk by mitigating the consequences—by preparing our health facilities and communities to treat the sick and protect the well. In the end, healthcare preparedness is about saving lives and reducing the long-term health consequences of disasters.

Why Government Programs Are Needed

Preparedness activities are expensive and do not produce offsetting revenue. Although they occur daily at the national level, disasters are low-probability events at the local level. The chance that any individual hospital will face a disaster in the next 5 years is small. So in the view of a hospital executive facing tight budgets, it is hard to make the business case for preparedness. We speak of this as the *parking lot conundrum*: Is it better to spend a million dollars on preparedness that might never be needed, or spend it on improving parking that will lead directly to more revenue in the short term? A strictly financial analysis might well favor the parking lot. But although the probability is low for an individual facility, the consequences can be extraordinary, as so vividly demonstrated after Hurricane Katrina[1] and to a lesser extent in the aftermath of Hurricane Sandy.[2,3] Getting back to the risk equation above, this means that the risk is higher than it may seem if one is just focusing on the probability. In many ways, preparedness is best thought of as insurance: paying a small regular amount to protect from the severe consequences of a disaster. Even knowing this, many hospitals choose to do only the minimum that is required. Consequently, over the past 15 years most of the progress in healthcare preparedness has come as a result of federal programs and the stricter accreditation requirements of the Joint Commission (the private entity that accredits most hospitals).

A Brief History of Federal Programs

The National Disaster Medical System (NDMS) has been in existence since the Cold War. It was originally designed to manage large numbers of military casualties from a foreign battlefield. It consists of 3 components: deployable teams of emergency medical responders, a network of private hospitals that have agreed to take evacuated disaster victims, and a transportation coordination system. While valuable, the magnitude of resources available from NDMS are insufficient for large-scale events and are dwarfed by the scale of the US healthcare system.[4]

The modern era of healthcare preparedness began in 1996 in response to increasingly frequent terrorism events in the 1990s, such as the 1993 bombing of the World Trade Center in New York City, the 1995 bombing of the Oklahoma City Alfred P. Murrah Federal Building, and the 1995 biological and chemical terror attacks by Aum Shinrikyo in Japan. The Metropolitan Medical Response Program (MMRS) was created at the Department of Health and Human Services (HHS) in 1996 but eventually transferred to the Department of Homeland Security (DHS). The program was designed to prepare communities for an attack by weapons of mass destruction. It created 127

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local jurisdictions in which agencies involved in emergency management, law enforcement, EMS, fire, and hazardous material planned together along with healthcare facilities.[5] The program has been defunded since 2011, although some local MMRS committees continue to exist and provide a basis for regional preparedness efforts.

At the hospital level, significant change occurred in early 2001 with the release of new, much stricter Joint Commission standards for emergency preparedness. These new standards were just being implemented when the 9/11 attacks occurred, followed immediately by the anthrax letters. Within months, HHS Secretary Tommy Thompson established an Office of Public Health Preparedness. Very soon this new office created the National Bioterrorism Hospital Preparedness Program (NBHPP) with a mandate to prepare the country's 5,000 hospitals for what was expected to be an imminent bioattack. Initially, the NBHPP was funded at approximately $500 million per year, and the funds were distributed to hospitals through cooperative agreements with state health departments.

In 2006, the Pandemic and All-Hazards Preparedness Act (PAHPA) was signed, replacing the Office of Public Health Preparedness with the new Office of the Assistant Secretary for Preparedness and Response (ASPR). Following the creation of ASPR, the NBHPP was changed to the Hospital Preparedness Program (HPP), with a broadened mission to address "all-hazard" healthcare preparedness. Over the past 10 years, the HPP has continued to evolve. Increasingly, the focus of the program has been on the development of healthcare coalitions (HCC) designed to foster emergency preparedness collaboration among hospitals and between hospitals and public health agencies, emergency management agencies, and emergency medical services. At the same time, its budget has been cut by approximately 50% from its 2003 levels.

In parallel with the HPP, the Centers for Disease Control and Prevention (CDC) launched the Public Health Emergency Preparedness (PHEP) cooperative agreement in 2002 to better prepare state, local, tribal, and territorial public health departments for public health emergencies. The funding for this program has decreased by a third over the years.[6]

Other federal preparedness programs touch the health sector as well but do not directly affect hospitals. These include, among others:

- DHS's Urban Area Security Initiative (UASI), which funds emergency management activities to build and sustain the capabilities necessary to prevent, protect against, mitigate, respond to, and recover from acts of terrorism in designated high-threat, high-density urban areas.[7]
- The CDC National Strategic Stockpile (SNS), which maintains the nation's emergency supply of drugs, vaccines, and medical supplies for use in a public health emergency.[8]
- CDC's Cities Readiness Initiative (CRI), which funds public health activities in 72 large cities to enable them to quickly receive and distribute emergency items from the SNS following a large-scale public health emergency.[9]
- ASPR's Medical Reserve Corps (MRC) program, which is a national network of local volunteer groups organized to help with aspects of health related to disasters.[10,11]

The newest entry in the spectrum of federal health preparedness initiatives is the Centers for Medicare and Medicaid Services (CMS) preparedness rule finalized on September 16, 2016. This rule establishes emergency preparedness requirements for facilities and suppliers participating in Medicare and Medicaid to prepare for disasters and coordinate with federal, state, and local emergency preparedness systems. This rule comes with no additional funding and little in the way of an enforcement mechanism.[12]

What We Have Learned

The investment in healthcare preparedness has produced positive results. This has been demonstrated in many disasters in recent years. Hospitals and public health are better prepared than they were before, and collaboration among hospitals, public health departments, emergency management agencies, and EMS has improved. But many challenges remain. Many coalitions are not well developed, and the reductions in federal funding threaten the progress that has been made. Health departments and hospitals struggle to find the money needed to maintain their healthcare coalitions and the essential functions they support, such as regional exercises and joint training, much less expanding their coalitions. Yet, maintaining healthcare coalitions and expanding them is important to the nation's health security.

Coalition building, however, is hard work. Hospitals are fiercely competitive and reluctant to share data and resources. Getting them to work well together has been a challenge. This has been complicated by the emergence of integrated health networks that merge multiple hospitals, physician offices, and other services into one large enterprise. A foundational business principle of these networks is keeping the patients and resources within the networks. This makes local cross-institutional coalition building more challenging. But these are not reasons to shy away from the challenge of coalition building; they are reasons to invest even more in promoting them. By eliminating redundancies and taking advantage of efficiencies of scale, healthcare coalitions are the best way to leverage limited preparedness funds.

This does not mean that healthcare preparedness should be solely a federal responsibility. States, counties, cities, and hospitals themselves have an important stake in having a well-prepared health system. But the investments by hospitals and localities are often less tangible than federal

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budgets and therefore harder to identify and track. Research is need to quantify the nonfederal contributions to healthcare preparedness.

Recommendations

- **HPP funding should be substantially increased to account for the many new entities that will be encouraged to join healthcare coalitions.**

A much broader segment of health-related entities are likely to be motivated to join healthcare coalitions because of the new CMS preparedness rule. This new unfunded mandate, while good for preparedness, creates additional financial burdens on these organizations and on the coalitions. These new costs, in addition to the already inadequate funding for maintaining coalitions, suggests that HPP funding should be increased by 50% to $375 million, which is still $125 million less than the program's funding at its peak.

The experiences of Hurricanes Katrina and Sandy demonstrate that many more components of the health sector than just hospitals and public health departments play important roles in the resilience of the healthcare system. This includes medical clinics, home health services, dialysis centers, behavioral health providers, and pharmacies, among many others. Until recently, there was limited outreach to these partners, and for the most part they have not been very engaged in preparedness activities. Hurricane Sandy showed how essential these parts of the health sector are to resilience. When these services failed during the hurricane, patients turned to the overburdened hospitals.

- **Novel funding mechanisms should be sought to incentivize community-based, grassroots organizations to become more engaged in preparedness activities in their communities.**

Businesses, philanthropies, and other private entities should be engaged as partners with governments in promoting disaster resilience at the community level. The president should declare that community resilience is a national priority and launch an initiative to kick-start such efforts. The federal government should pilot incentive programs to communities and community-based organizations to foster disaster resilience work at a grassroots level. One possible path is to experiment with competitive grants to local organizations funded through a combination of federal, state, private, and philanthropic sources.

- **ASPR should pilot an initiative to designate disaster specialty hospitals that can serve as centers of excellence in disaster care delivery and innovation.**

Because good preparedness is expensive, it may be more cost-efficient to consider a tiered system of preparedness in which every hospital and every community has a baseline level of preparedness but certain large institutions are designated as regional disaster specialty facilities. This is consistent with the way that trauma care is organized and with the tiered model that was developed for treating Ebola in the United States. It is important, however, that such an initiative not divert funding from the current HPP mission. A pilot project to assess the feasibility and cost of such a tiered national model should be considered.

This pilot project should be designed in collaboration with the Joint Commission and other relevant stakeholders. Competitive awards should be made to a limited number of highly motivated institutions.

- **States should create crisis standards of care plans informed by national guidance that include allocation of scarce resources.**

Despite the considerable progress to date, the nation remains inadequately prepared for a catastrophic event that sickens or injures tens of thousands—like a major earthquake, large-scale bioattack, or nuclear detonation. Much more work can be done to mitigate the consequences of such an event but it is likely that in any scenario like this, more people will need life-sustaining resources than there are resources available. Figuring out how best to allocate such scarce resources and implement crisis standards of care requires ongoing efforts across the country. While national guidance, such as that issued by the IOM[13] or the American College of Chest Physicians,[14] can be invaluable, plans must be implemented at the state and local levels. In addition to writing plans, considerable community engagement is needed to ensure that the public and healthcare providers are aware of such plans and have an opportunity to have input.

The drafting of these plans should be accompanied by community engagement efforts to educate the public and seek its input.

Building on Success

America is stronger and safer if its healthcare and public health systems are well prepared and its communities are resilient. The substantial progress that has occurred over the past 15 years can be built upon by continued investments in programs that have proven to be successful and by experimenting with some new approaches as outlined above.

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Strengthening the US Medical Countermeasure Enterprise for Biological Threats

Biological threats, which range from naturally occurring outbreaks of infectious disease to intentional acts of bioterrorism, pose unique dangers to public health and national security in the United States. Medical countermeasures (MCMs)—drugs, vaccines, diagnostic tests, and other therapies and devices—rank among the most important assets in the nation's arsenal against dangerous pathogens, as well as chemical, radiological, and nuclear threats. Communities with access to vital MCMs are better equipped to detect both accidental and deliberately caused outbreaks quickly, immunize susceptible populations, and treat infected patients, thereby alleviating the consequences associated with infectious diseases: illness and death, economic losses, societal unrest, and strained public health and healthcare delivery systems.

The United States relies on the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to develop, approve, purchase, and distribute the MCMs needed to mitigate biological threats and their impacts on health and security. PHEMCE, which is led by the Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), includes several HHS partners, including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Other interagency partners include the Department of Defense (DoD), the Department of Veterans Affairs (VA), the Department of Homeland Security (DHS), and the US Department of Agriculture (USDA). Among these entities, NIH (which includes the National Institute of Allergy and Infectious Diseases) is a driving force for early-stage biomedical research on infectious disease prevention and treatment. DoD operates a Medical Countermeasure Systems office that leads efforts to develop and field MCMs for military forces. Finally, the Biomedical Advanced Research and Development Authority (BARDA), part of ASPR, plays a key role in developing and procuring MCMs against a range of biological threats.

Several policy frameworks and pieces of legislation also govern US efforts in MCM acquisition, regulation, and distribution. Notable among these is the Project BioShield Act of 2004, which was created to fund development and government procurement of novel MCMs against traditional biological weapons threats such as botulism, anthrax, and smallpox. The FY2016 budget for HHS's Public Health and Social Services Emergency Fund included $646 million to support Project BioShield activities. The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), enacted in March 2013, authorized further funding for MCM purchasing and advanced MCM research and development efforts through 2018. Additionally, Homeland Security Presidential Directives 10, 18, and 21 (Biodefense for the 21st Century, Medical Countermeasures Against Weapons of Mass Destruction, and Public Health and Medical Preparedness, respectively) underscore the importance of a robust MCM enterprise to national and global health security.

With the support of federal policies and legislation, PHEMCE has made many critical contributions to preparedness and response efforts around biological threats. In response to the 2014 Ebola outbreak in West Africa, for example, PHEMCE partners rapidly coordinated efforts to develop and test needed vaccines, therapeutics, and diagnostics. In 2014, PHEMCE partners also procured 4 million additional doses of a next-generation smallpox vaccine, as well as 33,000 doses of a monoclonal antibody against anthrax toxin. Additionally, between 2014 and 2015, FDA approved 2 new influenza products, as well additional MCMs against anthrax, high doses of radiation, and plague.

Still, sustaining and furthering national MCM preparedness for biological threats remains a challenge for the nation. Bringing a fully licensed MCM from bench to bedside typically takes up to a decade or longer and close to a billion dollars. An evolving threat landscape further complicates efforts to prioritize MCM investments for different types of biological threats. Recent experiences with Ebola, Zika, Middle East respiratory syndrome coronavirus (MERS-CoV), and pandemic influenza have also highlighted a range of challenges: for example, that pharmaceutical manufacturers have little financial incentive to

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develop and produce MCMs against rare and emerging—albeit high-consequence—pathogens.

Given that most MCMs against high-priority biological threats lack viable commercial markets, there is considerable uncertainty regarding their development. As a result, MCM development for biodefense and emerging infectious diseases remains contingent upon government funding, unique incentive systems, and advance purchase agreements. Federal support for MCM research and development is a prerequisite for national security and preparedness. There are several steps the next administration could take to fortify the United States's MCM enterprise. These efforts, in turn, could enhance national readiness for biological threats, protect the public's health, and strengthen national security.

Recommendations

- **The President should request continued funding for basic research and investments in new technologies that could accelerate MCM development and production.**

The President's Council of Advisors on Science and Technology (PCAST), in its most recent report on US biosecurity, recommends greater funding for basic and applied research (including regulatory science) at HHS and DoD, which would begin at an initial level of $75 million annually for 4 years and gradually increase to $250 million per year. Such support is an important precondition for successful discovery and development of MCMs for biodefense.

PCAST also recommends setting an ambitious national goal: that a vaccine for a novel biological threat should be developed, manufactured, tested, and licensed within 6 months of identifying the threat and deciding to pursue a vaccine. NIH, the biomedical research arm of the federal government, should receive increased funds specifically designated for this foundational work.

In addition to supporting basic research for biological threats, the Administration should also increase investments in new technologies (eg, platform technologies and synthetic biology–based methods of rapidly creating diagnostics, drugs, and vaccines) that could accelerate MCM development and help scale-up MCM production during a public health emergency. Funds in support of this aim should be vested in BARDA, which develops technologies for advancing MCM manufacturing, and the Defense Advanced Research Projects Agency's (DARPA) Biological Technologies Office, which executes innovative biotechnology research efforts in support of national security.

- **The Administration should prioritize development and procurement of MCMs to address antimicrobial resistance, including nontraditional MCMs.**

Federal funding entities and research agencies need to prioritize MCMs needed to combat an evolving array of biological threats. R&D efforts should include a focus on creating point-of-care diagnostic tools, particularly for emerging or novel infections, as well as a strong focus on addressing antimicrobial resistance, given increasing resistance to current anti-infectives. New antibiotics and antivirals are needed, but research and development beyond traditional MCMs is critical. The Administration should continue to support efforts that aim to bring nontraditional MCMs to market. These include, but are not limited to monoclonal antibodies, bacteriophages, lysins, antimicrobial peptides, and microbiome-based products. The Administration should also continue to encourage federal scientists at BARDA and NIAID to identify nontraditional antimicrobials that qualify for fast-track approval, priority review, or accelerated approval pathways under the GAIN Act.

To alleviate the regulatory burdens associated with approving new MCMs, the new Administration should also encourage Congress to increase base funding for FDA to strengthen its Medical Countermeasure Initiative. These funds would enable the agency to grow and train its product review workforce; additional supplemental funds could also support FDA's ongoing regulatory scientific research efforts. Such support, in turn, would allow relevant FDA programs and offices to mobilize MCMs through the regulatory pipeline as efficiently as possible.

- **HHS should design and implement new incentive structures to accelerate public- and private-sector MCM research and development efforts.**

Certain incentives could spur innovation around MCMs that target drug-resistant pathogens, agents of bioterrorism, and emerging infectious diseases, while others may pose challenges. With the enactment of the 21st Century Cures Act, FDA will be tasked with overseeing a new priority review voucher program designated for MCMs against high-priority pathogens deemed to be national security threats, as well as other chemical, radiological, and nuclear agents. While such vouchers may offer pharmaceutical developers an added incentive to create needed MCMs for countering biological threats, conducting expedited product reviews over the specified 6-month period (as opposed to the typical 10-month period) could present FDA with considerable product review burdens. Increased base funding to strengthen FDA's product review workforce, as noted previously, could increase the agency's capacity to conduct expedited reviews of MCMs through this new program.

Initiating novel MCM development is only the first hurdle the nation faces in enhancing biothreat preparedness. Advanced or late-stage development is the costliest phase of the MCM pipeline and historically has been a major bottleneck in bringing viable products to market. The Administration could help bridge these late-stage gaps by increasing biodefense-related MCM funding through

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PAHPRA and Project BioShield—which are intended to cover costs associated with late-stage MCM development and procurement—thereby reducing some of the risks pharmaceutical manufacturers face in bringing MCMs to market.

Building public-private biosecurity partnerships could further strengthen research and development efforts at every point in the MCM value chain. The US government should create new opportunities for private-sector pharmaceutical companies to work with DoD and NIAID to translate basic research findings into investigational therapies, diagnostics, and prophylactics. The BARDA-NIH CARB-X accelerator, aimed at developing new MCMs in the face of antimicrobial resistance, is a recent example, as is BARDA's partnership with GlaxoSmithKline to develop novel antibiotics for combating both antibiotic resistance and the threat of bioterrorism. As these MCMs mature, further collaboration between manufacturers and federal entities that specialize in advanced development—such as BARDA's Centers for Innovation in Advanced Development and Manufacturing, or DoD's Medical Countermeasure Systems office—could help ensure that they successfully transition into the appropriate commercial markets.

- **The Administration should strengthen protocols for testing and approving MCMs for use during public health emergencies involving biological agents.**

The United States faces challenges in verifying the safety and effectiveness of MCMs for biodefense, as many cannot be ethically tested in human subjects. The Animal Efficacy Rule allows for approval of such MCMs based on evidence from animal studies; however, researchers still lack validated animal models for several high-priority diseases. The Administration should therefore fund federal biomedical authorities to continue collaborating with partners in academia and industry to identify additional animal models for basic research on emerging and intentional biological threats.

Another challenging problem, exemplified during recent outbreaks of Ebola and Zika, is that of generating enough interpretable clinical trial data to inform regulatory decision making around MCMs during ongoing emergencies. The Administration should encourage Congress to invest additional funds in creating and strengthening the infrastructure—personnel, trial sites, recruitment mechanisms, and the like—needed to conduct clinical trials efficiently both during acute public health emergencies and amid ongoing threats such as the spread of antimicrobial-resistant pathogens.

- **The Administration should strengthen international MCM sharing mechanisms.**

The United States is an important donor of MCMs during international public health emergencies, but often faces a myriad of legal, logistical, and financial barriers in sharing MCMs with nations affected by biological threats. During the 2009 H1N1 influenza pandemic, for example, the US government provided nearly 1 million doses of antivirals to affected nations through the Pan American Health Organization and pledged up to 25 million additional doses to the World Health Organization. In doing so, however, US health authorities encountered considerable challenges in establishing legal conditions with recipient nations. Assisting other countries in the control and containment of significant infectious disease outbreaks is in the United States's public health and national security interest. In this vein, the Administration should identify strategies for clarifying, codifying, and strengthening international MCM sharing protocols. Given an increasingly globalized world, having stronger national capacities to mitigate biological threats outside the United States lessens the risk of those threats gaining a domestic foothold.

The threat of natural and deliberate infectious disease emergencies are ever present and, by their very nature, evolving at a rapid pace. Ensuring that a robust and innovative MCM enterprise is poised to meet these challenges is the chief means of enhancing the national and health security of the nation and its people.

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Assessing and Addressing US Health Security Risks

There are a range of worrisome threats to US health and national security—worrisome because they have the potential to cause widespread disruption and damage to the public's health and to the US and global economies. These threats include major natural hazards like large earthquakes and hurricanes and infectious disease pandemics; accidental threats, including technological failures, such as nuclear power plant disasters like Three Mile Island and Fukushima; and intentional attacks by thinking adversaries, including terrorist use of biological, chemical, or nuclear/radiological weapons.

Securing the United States against threats to health and security inherently involves tradeoffs. Not every health security – related threat carries the same level of risk to the country, and not every government program addressing those threats can have top priority.

So, with many and varied health security threats and with limited resources to address them, it is important for the United States to have a clear process for determining risks and tradeoffs in a way that affords the public the most protection we can offer. Utilizing our best risk assessment methodologies is an important part of determining risk and setting national priorities.

Risk assessment is useful both for understanding the range of possible health security challenges the country might face (eg, possible disaster/outbreak scenarios) and for gathering data and knowledge about threats, which may help security and public health experts prepare and respond if something does occur. It involves a systematic evaluation of the likelihood (probability) of an event occurring, as well as of the consequences that result when a disaster does happen (eg, illnesses, injuries, deaths, and economic disruption).

A purposeful risk assessment process can help leaders compare the severity of different types of health security risk and can inform decisions about where funding and resources are most needed. Risk assessment allows decision makers to view a wider range of risk scenarios and examine them systematically. Without a formal process to assess risk, decision makers often rely on personal experience, which is inherently limited (we are only human after all). Conducting a risk assessment that systematically compares likelihood, vulnerability, and consequences for different scenarios helps reduce individual and group biases, which can prevent decision makers from seeing the full picture of risk before decisions are made.

Risk assessment is currently carried out by a variety of federal, state, and local government agencies for important but varied and delimited purposes. For example, the Department of Homeland Security (DHS) conducts chemical, biological, radiological/nuclear, and integrated CBRN terrorism risk assessments to understand the relative likelihood and consequences of terrorism use of any CBRN agent or weapon to attack the United States; the Department of Defense (DoD) assesses the variety of threats to military personnel and assets in the United States and abroad; and state and local public health and emergency management agencies undertake threat and hazard identification and risk assessments to understand and prepare for the most likely and consequential disasters at the local level.

All of these, and other ongoing risk assessment efforts, are important and contribute to our understanding of specific threats, vulnerabilities, and risks to national security and human health. However, they are conducted separately, with limited coordination among them. There is not currently a national-level risk assessment that compares all of the threats to national health security that we worry about, all in one place, so that they can be compared, contrasted, and the results used to help determine national health security priorities for our government.

Yet, while a national-level cross-hazard strategic risk analysis does not currently exist for the United States, there are past efforts here and current practices in other countries to look toward for inspiration. For example, in 2011, DHS conducted a one-time Strategic National Risk Assessment (SNRA) in support of Presidential Policy Directive 8 (PPD-8), to inform creation of a National Preparedness Goal, System, and Report. Through this process, the SNRA identified and gathered likelihood and consequence data on ''national-level events,'' including naturally occurring hazards, accidents and technological disasters, and intentional events, and conducted a subject matter expert risk

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assessment to determine their relative risk. This SNRA process was conducted at the national level, but it was not tied directly to program planning and has not been revised or repeated since that time.[1]

Outside of the United States, both the Canadian and British national governments produce annual risk assessments of ''civil emergencies'' or ''all-hazards'' that include natural, accidental, and malicious/intentional disasters.[2,3] These assessments incorporate historical data, threat information, and expert knowledge and opinion and provide rankings and recommendations for action to address risks identified in the process. The results of these assessments are intended to inform policy formulation and resource decisions that drive priority setting for national agencies responsible for executing programs.

A national risk assessment, such as the examples described above, could be a powerful tool to aid in decision making, but it will also have its limitations. Risk analysis depends on data and evidence, which are not always available (especially for rare events that we seldom or have not yet experienced as a country). As a result, conclusions from risk assessment can be highly uncertain and should not be the sole basis of any decision. However, having a national risk assessment would make it more likely that we will identify and then allocate resources effectively to prepare for and respond to the next health security threats we face.

Recommendation

- Establish a national risk assessment process for the United States.

What is needed is a comprehensive, strategic-level US risk assessment that identifies and compares all major threats to the homeland, including all types of terrorism, natural disasters, naturally occurring epidemics, and technological disasters that would have a significant impact on our national security if they were to occur. The White House has a unique government-wide perspective on health security risk and a unique position from which to coordinate and direct federal health security programs. Therefore, it is appropriate for the White House to initiate and lead a national risk assessment process. A first step in this process would be for the White House to convene an advisory committee, including experts in risk assessment, public health, medicine, and national security, to determine the agency or agencies that should implement the risk assessment, what risk analysis methods will be used, and how often the assessment should be updated and revised.

There are a number of risk assessment methodologies that could be applied to a national risk assessment, from a fully quantitative analysis to a fully qualitative assessment based solely on expert judgment. The examples above from the US, UK, and Canada used various combinations of quantitative and qualitative methods, combining data or data-driven estimates collected about likelihood/frequency and consequences of events with subject matter judgment about how those identified risks should be ranked and prioritized. A similar method would likely work well for a new US national risk assessment.

Finally, once this risk assessment process is set and is being used, it will be important to revise the risk assessment, and review the methods, inputs, and focus of the assessment regularly to ensure that it is rigorous and helpful to understanding and addressing health security risk.

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Improving Biosurveillance Systems to Enable Situational Awareness During Public Health Emergencies

Over the past 10 years, US health security has been threatened by a series of infectious disease events: the 2009 influenza outbreak, the emergence of Middle East respiratory syndrome (MERS), the Ebola outbreak in West Africa, and the rapid spread of Zika virus throughout the Americas. In each of these events, inadequate information has delayed initial detection of the outbreak, and a lack of understanding about the underlying epidemiology of the viruses hindered control efforts. As the ongoing US response to Zika illustrates, delays in detecting and responding to outbreaks can exacerbate their human and economic tolls. While the United States continues to struggle to understand how Zika virus can spread and cause serious disease, more than 37,000 cases have already been identified in the United States and its territories.[1] Each one of these cases must be investigated by health authorities to ensure that they do not spread their infection. In particular, pregnant women must be followed closely, as Zika can cause fetal death or severe birth defects. It is estimated that each baby who is born with Zika-related birth defects will cost families and the US healthcare system up to $10 million.[2]

The continued challenge that the United States faces in detecting and knowing how best to respond to acute infectious disease threats like Zika should encourage a closer analysis of our current biosurveillance capabilities and spur action toward much-needed, sustainable improvements. Biosurveillance generally refers to the continued monitoring of information sources for the purposes of detecting and managing an outbreak or other public health event, whether naturally occurring or deliberate. Biosurveillance systems may gather and analyze data from a variety of human, animal, plant, and environmental health sources. The goal of this activity is to provide situational awareness—an understanding of what is going on—with respect to the occurrence of biological threats and to guide efforts to control them.

Since 2001, the federal government has made considerable investment in deploying biosurveillance systems across the country with the goal of providing early detection of and situational awareness during public health emergencies. Federal support has vastly improved the state of surveillance in the United States. The nation now benefits from having a network of more than 150 public health laboratories that can detect a biological attack and outbreaks of other diseases of public health significance.[3] Additionally, the majority of health departments in the United States now have a mix of traditional disease-specific and more timely syndromic surveillance systems in place to monitor disease trends and to provide situational awareness during public health emergencies.

Despite these important advances, there remain fundamental gaps in the ability of existing biosurveillance systems to support real-time decision making during public health emergencies. In 2012, the White House attempted to address these shortcomings by releasing the National Biosurveillance Strategy. This document established the important expectation that biosurveillance systems will be able to (1) rapidly alert and inform decision makers of potential incidents of national significance; (2) continually provide critical updates as circumstances evolve; and (3) access information that answers decision makers' questions about probable impacts of an event and the consequences of action/inaction.

The National Biosurveillance Strategy did not offer details on how this vision for biosurveillance was to be implemented, but it called for the development within 120 days of an Implementation Plan. To date no such plan has been released.

As a matter of priority, the next Administration should work to improve our national biosurveillance capabilities in the following ways.

Recommendations

- **Enhance support for state and local health departments.**

State and local surveillance programs are the foundation of our national biosurveillance enterprise. The federal government's capacity to detect and maintain situational awareness

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during catastrophic events depends on the ability of state and local agencies (particularly health departments) to build and maintain robust and flexible biosurveillance systems. However, national biosurveillance capabilities are threatened by shortfalls in state and local financial resources. Limits in state budgets make it difficult for agencies to maintain information systems and staff solely with local resources. The Centers for Disease Control and Prevention (CDC) public health emergency preparedness cooperative agreements have been essential sources of support for state and local health departments to enable them to develop and maintain basic biosurveillance capabilities. While federal preparedness investments have been an important first step, the level of federal funding for biosurveillance appropriated to date is not commensurate with the strategic national importance of these systems. Failure to increase support for health departments will erode critical progress made to date toward ensuring that basic biosurveillance capabilities exist across the United States.

Above all, the US government must ensure that there are adequate numbers of competent personnel to run biosurveillance programs, particularly at state and local health departments. Unfortunately, continued cuts in federal preparedness funding over the past 10 years have forced state and local health departments to scale back on important preparedness programs. These cuts, combined with state budget deficits and layoffs, have exacerbated existing shortages of highly skilled and competent public health personnel to build and maintain biosurveillance systems. Ensuring the functioning of critical biosurveillance programs will require sustained and committed federal support for biosurveillance programs, including adequate and flexible funding to hire and retain biosurveillance analysts.

- **Provide critical electronic health record data to public health departments.**

Real-time exchange of patient-level data between clinical and public health communities is critical for detecting and responding to public health emergencies. Public health departments need detailed data about patients who are affected in order to understand key aspects of the outbreak. While there has been a concerted effort and significant funding allotted to developing electronic health records and to encouraging their adoption by medical providers, far less attention and funding support have been allocated to making sure the information contained in electronic health records is available to public health departments. While some public health departments may receive some electronic data from electronic health records, such as immunization records and laboratory reports, few have the ability to access electronic health records in real time and in a flexible, query-based way that is likely to provide the answers necessary to quickly get on top of a public health emergency as it unfolds.

As an immediate priority, the HHS Office of the National Coordinator for Health Information Technology (ONC) should work with CDC and the Centers for Medicare and Medicaid Services (CMS), together with input from state and local public health stakeholders, to define and implement national data standards to improve public health departments' access to electronic health records during public health emergencies. CDC should work with state and local stakeholders to determine how to best access and use essential public health data contained in electronic health records in a manner that assures the security and confidentiality of patient information.

- **Assess the ability of biosurveillance systems to support decision making.**

The next Administration should preserve the National Biosurveillance Strategy and release from the White House a plan for its implementation. At a minimum, the implementation plan should contain an analysis of where existing biosurveillance systems fail to provide sufficient information to support decision making. To complete this analysis, US agencies should work with states to define a minimum set of information that will be needed to manage a public health emergency and then map this information against existing biosurveillance systems.

This analysis will likely identify deficits in the ability of existing surveillance systems to provide logistical information needed for mounting a response to a public health emergency. Experience in previous emergencies has shown that while most public health surveillance systems focus on data related to the number of infected patients, they often lack data pertaining to availability of hospital beds, pharmaceuticals, personal protective equipment, and other medical supplies that are necessary to make informed decisions about how best to respond to a public health emergency. The US government could bring these and other information needs to the private sector and identify potential ways to collect that data and create data-sharing provisions (eg, confidentiality agreements, de-identification steps, etc) needed to share this information with response agencies.

- **Integrate animal, environmental, and human health data.**

The recent Ebola epidemic in West Africa demonstrated an important deficiency in biosurveillance: the integration of human, environmental, and animal health surveillance data. Though the outbreak caught many political leaders and public health experts by surprise, existing wildlife data indicated that a human outbreak in the region was possible.[4] Despite known important linkages between animal and environmental health in determining the occurrence of events, like the Ebola epidemic, that threaten human health, there continue to be insufficient efforts to integrate knowledge and data from across these sectors.

The US government should work to improve the integration of human, animal, and environmental data. An important first step will be to increase support for existing surveillance programs that have already demonstrated success, such as ArboNET, which provides important data on the

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occurrence of Zika, West Nile, and other viruses. Additionally, the US government should give serious consideration to the recommendation, which was made by the bipartisan Blue Ribbon Study Panel on Biodefense, to create a Nationally Notifiable Animal Disease System.[5] Finally, the US government should improve the integration of the food-related surveillance initiatives that exist across the federal government. There are many different, separate national surveillance systems that, if integrated, could provide a better understanding of the occurrence and possible causes of foodborne illness outbreaks. Federal agencies should digitally connect and automate the comparisons of data from the food, animal, and human health surveillance programs that are operated by CDC, FDA, and USDA, which may provide an earlier indication of a link between human and animal infections. At the very least, there should be a way to directly compare isolated patterns that are in animal and human health surveillance programs. CDC's PulseNet and USDA's VetNet programs should be linked and equipped to automate analysis of these 2 data streams for evidence of similarities that may indicate a common exposure.

- **Enhance laboratory capacity and improve the availability of diagnostics tools.**

As we have seen in the current Zika crisis, the ability of the United States to conduct surveillance for and respond to emerging infectious disease outbreaks is severely compromised when there are insufficient tools for accurately determining who has been infected. It has been reported that because of laboratory backlogs, pregnant women in Florida have experienced delays in getting the results from tests to determine if they have been infected by Zika. Diagnostic delays such as these not only compromise care for women and their unborn children, but hinder our abilities to conduct epidemiologic investigations to determine whether and how the outbreak may be spreading. Increased support for public health and clinical laboratories is needed to ensure there is adequate surge capacity during crises.

The current Zika crisis also underscores that new diagnostic technologies are needed. Currently, it is not easy to determine if someone has been infected with Zika unless they are within a small window of time after the onset of symptoms. The inability to determine with confidence whether someone was infected with Zika in the past makes it difficult to counsel patients and interrupt transmission. The US government should expand current support for efforts to develop new diagnostic technologies for Zika and other important public health threats.

- **Promote open data.**

During one of Europe's deadliest *E. coli* outbreaks, sequence data from the outbreak strain was shared publicly, and crowd sourcing enabled the data to be analyzed more quickly than traditional approaches would have allowed. While the world is undergoing a big data revolution, in the United States a current bottleneck in biosurveillance analysis is lack of good tools and a skilled workforce to support better analysis and visualization of biosurveillance information, particularly data that exist outside of traditional public health surveillance streams. The United States should take advantage of the wisdom and talent of the crowds to improve the analysis and visualization of biosurveillance information by making anonymized surveillance data publicly available. Publishing de-identified surveillance data in as close to real time as possible would enable interested citizens to develop applications to enable enhanced analysis of biosurveillance information.

CONCLUSION

What the past decade has shown us is that the continued occurrence of infectious disease events is all but inevitable. As the pace of globalization and international travel increases, new diseases will continue to emerge and spread. Our best defense against these events is to have in place systems that will quickly detect their occurrence and to improve understanding of what is needed to stop them. Without effective biosurveillance systems, political leaders will have little information to guide decisions about what measures should be taken to ensure that small outbreaks don't go on to become costly epidemics and what measures would be likely to exacerbate the toll of the event. Though important strides have been made toward development of these systems in the United States, critical gaps remain, and eroding financial support for biosurveillance threatens to undermine progress made to date. To ensure it has the best information available to successfully manage the infectious disease events that will inevitably occur during the next administration, the US government should expand its support for the biosurveillance mission.

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STRENGTHENING US PUBLIC HEALTH PREPAREDNESS AND RESPONSE OPERATIONS

IN THE YEARS FOLLOWING THE 9/11 attacks, the leadership, resources, and expertise that public health agencies across the country can bring to bear on the response to infectious disease emergencies and other catastrophic events took on additional urgency and importance. In light of this expanded mission, Congress appropriated funds to support public health preparedness at the state and local levels, one result of which was the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) program. Several recent infectious disease emergencies—chief among them the Ebola epidemic in West Africa and isolated cases in the United States (2014-15) and the ongoing Zika virus pandemic—have challenged national health security and demonstrated a need for continued investment in domestic public health preparedness and response infrastructure.

Recommendations

- **Provide increased funding for the Public Health Emergency Preparedness program.**

Federal support remains vital to national preparedness for a range of intentional, accidental, or naturally occurring epidemics, and real gains have been made since 2001. The CDC reports that all or nearly all health departments in the country are currently able to mobilize staff to respond to an emergency, collaborate with healthcare providers for the purpose of preparedness planning, and distribute medical countermeasures (ie, the therapeutics and vaccines needed during an emergency), which was not the case in the pre–9/11 era.

Declining federal support for public health preparedness, however, puts these gains in jeopardy. Specifically, funding for PHEP has decreased by 40% from its peak in FY2006.[1,2] The effects of these cuts are being felt nationwide, as health departments have been forced to make significant reductions in staff and preparedness activities. According to the National Association of County and City Health Officials, more than 51,000 jobs have been lost at local health departments since 2008.[3] These cuts translate directly to a decreased ability to mount a timely, effective response to routine and extraordinary threats, including infectious diseases, natural disasters, and terrorist incidents. To ensure the maintenance of key public health preparedness infrastructure, funding for this program should be restored to FY2006 levels, or approximately $1 billion per year.

While preparedness has been historically difficult to measure in absolute terms, tools like the recently developed National Health Security Preparedness Index can be used to assess progress in this area and potentially to help guide resource allocation decisions. Ultimately however, in an increasingly constrained financial environment, federal funds for preparedness should be prioritized for those localities judged to be at highest risk.

- **Ensure support for the provision of clinical care for infectious diseases.**

Public health clinics contribute significantly to the nation's outbreak response capabilities and should be supported as a matter of priority. At many health departments, clinical staff that typically provide care for patients with routine conditions, such as tuberculosis and sexually transmitted infections, are important sources of surge capacity for responding to public health emergencies, such as those posed by Zika, Ebola, MERS, chikungunya, and dengue. Public health clinicians who work to interrupt disease transmission on a daily basis have the necessary skills and experience to lead or support disease control activities like outbreak investigations, mass vaccination campaigns, public education, and others. For example, public health clinicians who work on reproductive health in their daily duties formed teams that went door to door in Miami, Florida, to conduct surveillance for Zika virus infection. But budgetary constraints have forced many health departments to scale back or shutter public health clinics where these vital personnel operate.

As discussions about the future of the Affordable Care Act progress, the Administration should work with

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Congress to ensure that future healthcare legislation enables patients with infectious diseases that pose a significant threat to the public's health to have access to care. It is critical that cost concerns not stand as a barrier to care for patients with communicable diseases. Cost barriers such as high deductibles and copayments can preclude even those covered by health insurance from seeking care, prolonging the course of their disease and increasing the likelihood of community transmission.

Services for these diseases—including screening, diagnosis, treatment, and case management—should be covered without cost-sharing for patients, regardless of their insurance status or where they seek care. For those insured patients who seek care at a public health clinic, that health department should be permitted and able to submit for reimbursement to ensure that they can continue providing such services. The identification and treatment of patients with infectious diseases is critical to interrupting transmission, and ensuring access to care is essential for the protection of the public's health.

➢ **Establish a public health emergency fund.**

Once an event has triggered a local, regional, or national public health emergency, health departments shift from preparedness to response activities. While the specific response activities implemented by health departments depend on context, examples include the ability to rapidly vaccinate or distribute medications to a given population, conduct outbreak investigations and surveillance, and communicate risk information to the public.

In addition to sustained funding to maintain the core public health infrastructure that supports preparedness programs, additional funding is needed during the response to public health emergencies. Public health authorities have historically depended on the provision of an emergency appropriation by Congress to finance the response to infectious diseases like H1N1 influenza and Ebola; however, this reliance on emergency appropriations can lead to dangerous delays. Delays in the availability of funding created significant challenges in responding to Zika infections occurring in the United States. In Florida, which had seen local transmission of Zika, patients were forced to wait for weeks for their test results because of insufficient laboratory capacity in the state. Now that an emergency appropriation has been passed, the challenges caused by a delayed response are not likely to abate in short order, as health officials have said that it may be several more months before states receive federal funding.

To ensure that public health can respond effectively and in a timely manner to future health crises, Congress should enact a modern Public Health Emergency Fund. Based on past emergency appropriations, our own analysis, and that of expert advisory groups such as the President's Council of Advisors on Science and Technology, we recommend an appropriation in the amount of $1-2 billion. Such a fund should be maintained separately from federal preparedness grants, be made available immediately upon declaration of a public health emergency, and be of a magnitude sufficient to jumpstart a nationwide response to a recognized threat.

➢ **Build an emergency medical team for use during epidemics.**

Finally, the Administration should direct the development of a deployable team capable of providing clinical care surge capacity for use during epidemics and disasters. The West African Ebola epidemic clearly demonstrated that the nation lacks the ability to rapidly support the provision of clinical care in an emergency and was dependent on nongovernmental organizations to conduct this critical response activity. The rapid deployment of healthcare providers to the scene of an outbreak could, as part of a broader health response, aid in achieving epidemic control by treating patients (thereby interrupting disease transmission), training local healthcare providers on infection control measures, and capturing and disseminating pertinent clinical observations and treatment protocols. Such an emergency medical team would be an asset domestically and internationally, in support of the WHO's Global Health Emergency Workforce.

In conclusion, it is impossible to know with certainty the location and nature of the next challenge to our national health security. However, it is safe to assume that one or more events that require a national-level response will occur in the near term. As a result, ensuring a high degree of public health preparedness should be a national priority.

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Partnering with Communities to Foster Trust, Save More Lives, and Prompt Recovery in Epidemics and Disasters

Beginning in 2017, new federal leadership can take important steps to vitalize the role of private citizens and businesses as well as faith-based and community-based organizations in the larger public health emergency preparedness (PHEP) enterprise. A broad consensus exists that government on its own cannot effectively and equitably manage epidemics and disasters. Past events repeatedly demonstrate that actions by citizens and civic groups have helped to curtail the impacts of extreme events and to prompt a more complete recovery from mass trauma. Nonetheless, the full potential of nongovernment forces in disaster readiness, response, and recovery has yet to be realized. Community engagement can enhance the quality of emergency planning, improve protections for vulnerable populations, multiply preparedness and response assets, and, ultimately, save more lives. The incoming administration in concert with Congress has an immense opportunity to enhance the country's resilience to catastrophic health events by steadily investing in robust partnerships between local public health authorities and the communities they serve.

Recommendations

- **The Administration should use the bully pulpit to validate forcefully and consistently the whole community's role in helping manage disasters and epidemics.**

The new Administration should set the tone—to be carried on down to state and local elected officials and to their public health and safety advisors—that government should partner with private citizens, local communities, nonprofits, and businesses in the management of disasters and epidemics. Research suggests that the intangible quality of leadership plays a decisive role in helping build effective collaborations for population health. Strong, dedicated leaders who project a vision, inspire commitment, promote inclusion, empower staff, value innovation, and allocate resources have been an essential ingredient for successful private-public partnerships working on behalf of community health, including public health emergency preparedness.

Fueled in part by distorted news reports and Hollywood depictions, myths about unstable mobs in disasters linger, despite progress in thinking in recent years. Incoming leaders should preserve the gains made in understanding and capitalizing on citizen and civil society contributions during extreme events. Decision makers, for instance, should resist thinking that members of the public are panicking when they are merely engaging in understandable behaviors, such as searching for more information, questioning authorities, and adopting precautionary measures (even if officials judge these actions as unfounded). Research suggests that rather than being overwrought by an impulse for self-preservation at the expense of others, people engage in altruistic behaviors during disasters: Most people recovered from the wreckage of an earthquake, for instance, are saved by bystanders and nearby associates rather than search-and-rescue professionals.

Though an epidemic of novel disease may initially unnerve people, such reactions diminish as communities evolve coping strategies. Moreover, volunteers have played essential roles during major outbreaks of such scary diseases as smallpox, polio, Spanish flu, and HIV/AIDS—from staffing mass vaccination clinics, to helping the homebound, to influencing policies for disease prevention, vaccine development, and care delivery.

Federal leadership should model a resilience-building communication approach for decision makers at all levels to adopt throughout the crisis life cycle. Research suggests that during periods of everyday calm, people presume a state of safety and believe that a disaster will never happen, but if it did, it would affect others and not them. Leaders can temper this sense of invincibility with meaningful advice

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about proactive measures that people can take, individually and collectively, to diminish potential impacts: for example, family reunification plans, flood and earthquake insurance, neighborhood organizing, support for local bonds that underwrite structural mitigation projects.

During the crisis, top officials can avoid withholding information out of fear that people will panic, and instead provide steady updates, personal protective guidance, and details on volunteer opportunities to promote creative coping. Following the disaster, empathetic leaders can help ease distress by conferring meaning on the mass tragedy, focusing on the future, and underscoring collective learning. Moreover, they can take advantage of the window of opportunity that emerges when an otherwise theoretical threat has become a reality and people are primed to hear and act on prevention and mitigation advice.

- **The Administration should work with Congress to endow resource-starved local health departments with greater capacity to build community resilience partnerships.**

Government public health agencies are the glue that holds together society's preparedness and response system for disasters with health impacts. National thought leaders have consistently affirmed that the public health preparedness system includes individuals, communities, and businesses and that government public health agencies are accountable for system integration. Since the 9/11 and anthrax letter attacks, state and local public health departments have received PHEP financial and technical support from the federal government to prepare their jurisdictions to respond to disasters. Among the priorities of the PHEP grants program are risk communication; coalition building with business, faith-, and community-based organizations; incorporating public input into emergency plans and problem-solving sessions; and enlisting volunteers in everyday as well as emergency health and safety initiatives. Core principles of public heath practice further reinforce the obligation of state and local public health to work alongside and not independently of community members and their top health concerns.

To work *with*, not *for* the community in relation to preparedness and response, local health departments require sufficient organizational capacity. A key resource is a skilled, dedicated, and culturally competent staff who can develop an overall community engagement strategy, conduct broad public outreach and education efforts, design and deliver influential social media campaigns, and expend the face-time needed to build up trusted and lasting connections with grassroots groups and among vulnerable, underserved groups. A steady, ample budget is also necessary for successful community engagement. Expenditures include free training sessions and "giveaways" (eg, hand sanitizer, emergency backpacks) that hook people on preparedness; surveys, informant interviews, focus groups, translation services, and ethnic media "buys" that improve preparedness communication with diverse audiences; mini-grants to under-resourced organizations to catalyze interest in preparedness, raise employee and client preparedness levels, and support continuity of operations planning to meet client needs in an emergency; and formal processes to elicit public input into key policy decisions, such as how best to use scarce medical resources in a disaster. Agency leadership that prioritizes community engagement and inspires staff to work diligently on public involvement is another important ingredient for agency success.

Despite being a core feature of national health security, community engagement in emergency preparedness has been under-resourced, as part of a larger, perilous trend the new Administration should now turn around. In 2015, the National Association of County and City Health Officials (NACCHO) reported that local health departments had eliminated nearly 52,000 positions since 2008 due to layoffs and attrition in connection with hiring freezes or budget cuts. The Great Recession has produced lingering budget reductions, and nearly 1 in 4 local health departments is still affected by cuts today. In 2012, 15% of local health departments reported a reduction or elimination of emergency preparedness programs, on top of an earlier loss among 23% of local health departments in 2011. Federal PHEP funds have shown an overall trend of decline since the program's inception; in 2014, a majority of local health departments indicated their emergency preparedness funding comes only from federal sources. Community engagement is time and labor intensive work, yet it provides a high social return on investment. State and local health departments and their federal partners can benefit from having PHEP grant funding restored to original levels.

- **CDC should further motivate community- and faith-based organizations, especially those working among vulnerable populations, to integrate disasters into their mission.**

Vibrant grassroots organizations characterize every hometown: They give voice to collective needs, facilitate mutual aid, deliver social services, confer an identity and sense of belonging, and serve myriad other social functions and enjoyments. Neighborhood groups, senior centers, ethnic cultural centers, social service nonprofits, fraternal organizations, unions, faith communities, and other civic-minded associations can harness their leadership structures, communication networks, and command of local knowledge for the management of disasters and epidemics, thus complementing government's efforts. Among the roles that they can play are representing their members' interests in emergency planning sessions, amplifying and translating pre-event education and crisis communication messages, developing their own continuity of operations planning, providing emotional support amid mass tragedy, converting meeting halls into places of refuge, and rallying volunteers to backfill emergency response personnel during a crisis.

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Past and present events underscore the important contributions of civil society groups in a crisis. During the 2014-15 Ebola outbreak, Translators Without Borders enlisted a network of volunteer translators to provide basic messages, posters, public service announcements, and "voice over" in the local languages for the most affected populations of Guinea, Mali, and Sierra Leone. After Hurricane Katrina in 2005, some New Orleans residents were wary of rebuilding because demolition, debris removal, and reconstruction seemed too daunting; exchanges among neighbors of labor, tools and equipment, expertise, shelter, and childcare, however, conveyed commitments to the community's future well-being and made rebuilding a material possibility. During the 1947 smallpox outbreak in New York City, officials vaccinated more than 6.3 million people over a 4-week period, enlisting private physicians, Red Cross volunteers, teachers' groups, women's clubs, and civil defense groups to staff free clinics in 12 hospitals, 84 police precincts, and every public and parochial school.

Similar to strengthening local health departments' ability to engage community partners, grassroots groups need sufficient capacity to work effectively with public health and emergency management agencies. The incoming Administration, via the PHEP grants program administered through CDC or even a novel program to strengthen the country's resilience from the bottom up, should provide financial and technical support to civic-minded groups for readiness, response, and recovery purposes. Should the proposed support be administered through the existing PHEP program in the form of mini-grants, health departments should receive adequate funding, grant-making flexibility, and a clear mandate to apportion capacity-building aid to their grassroots partners. Nonprofit groups may be unable to participate in meaningful disaster-related activities if it means diverting their otherwise scarce resources to yet another mission. Capacity-building resources should be targeted especially to nonprofits embedded in underserved minority populations, where cultural norms, language requirements, and social connections may not be well understood by mainstream institutions.

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A Biosafety Agenda to Spur Biotechnology Development and Prevent Accidents

Biosafety—keeping laboratory workers, the community, and the environment safe—is a crosscutting need for all research activities, as well as an important research and policy area with medical, political, and security consequences. As such, it requires a dedicated plan for the US government. One reason biosafety is attracting more attention now is because it may be a limiting factor in the development of advanced biotechnologies. Many potential new biotechnology applications with biomedical and economic implications are intended to be used outside the laboratory and released into the environment, so their safety cannot rely on traditional laboratory containment. They are meant to be "outside." Applications such as mosquito control, agriculture, pollution remediation, mining, biofuels, medications that use synthetic organisms to treat gastrointestinal diseases, or even the recreation of extinct animals require synthetic organisms to be in the environment, where they can interact with other living things. These applications may be tremendously beneficial and may spur economic development, but if biosafety risks are not addressed and carefully thought through, they could yield unintended and accidental consequences.

Biosafety has become more politically important in recent times as well, particularly after multiple high-profile safety failures at federal and military laboratories involving smallpox, anthrax, and flu. In 2014, decades-old glass vials containing live variola (smallpox) virus were discovered at the US Food and Drug Administration (FDA). Smallpox was declared eradicated in 1980 and is supposed to be held only under tightly controlled conditions at the Centers for Disease Control and Prevention (CDC) and a designated Russian laboratory. Given that decades have passed and the samples were not either transferred or disposed of, this incident was indicative of poor inventory management. In 2015, it was discovered that the US Army Dugway Proving Ground had shipped samples containing live anthrax to centers not registered to work with it. These samples were incompletely irradiated, and some vials still had live anthrax spores. Additional potential exposures of anthrax and noncirculating influenza at the CDC occurred as well.

A series of comprehensive reforms affecting biosafety have already begun under the Obama Administration. Reform was motivated by laboratory incidents, but also by mounting concerns about the increased power and democratization of biotechnology: Consequential bio-errors may occur more frequently if more people are able to work on infectious diseases. If a laboratory accident occurs with a transmissible pathogen, the consequences could spread well beyond the laboratory—and beyond national borders. Many of these much-needed government reforms to biosafety are still in the process of being implemented. Yet, there are additional, new opportunities that will be important to pursue to increase safety in the coming years, including dedicating research funds to biosafety; expanding biosafety training into new environments, to reach the growing populations of people who are performing biological work; and leading the world to develop international biosafety norms.

Recommendations

- **Biosafety information is needed in order to advance biotechnology as well as to prevent laboratory failures, but little is currently being funded or performed. For safety, economic, and political reasons, the US government needs to fund biosafety research.**

Advanced biotechnology products will not be of any medical, manufacturing, or economic benefit if they can't be proven to be safe. In order to realize the benefits of biotechnology, there is a stark need for specific safety studies for advanced biotechnology products, including synthetic organisms used for environmental remediation or medicines that could theoretically remain in the environment

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after they are no longer needed, so that they can be safely used outside traditional laboratory settings.

One approach to containment outside the laboratory is called "intrinsic" biosafety—that is, the biosafety is built into the organism, so that the synthetic organisms can't escape boundaries that are set for them, even if they are outside of the laboratory. Some forms of intrinsic biosafety involve engineering organisms so that they are not able to survive without specific human intervention, such as by supplying a nutrient that is essential for life. If the nutrient is not supplied, the synthetic organism will die, and it will stay "contained" in the area where that essential nutrient is supplied. Early attempts to develop intrinsic biosafety were often unsuccessful and had high "escape" rates, because they relied on a single point of failure. Newer intrinsic biosafety approaches are more subtle and rely on combinatorial complexity, which drastically reduces the rates of failure and escape—that is, many safety systems would have to fail before the organism could escape. Some intrinsic biosafety work has been initiated by DARPA, but much more is needed if promising biotechnology advances are going to be translated into real products.

There is also a great need for data to reduce and prevent accidents in the laboratory. The need for data that describe laboratory incident and accident rates is well understood—How can problems be addressed if the incidence and causes for safety failures are not known?—and efforts are under way in the US government to set up a no-fault reporting system modeled on one used in the aviation industry to reduce accidents.

However, more information related to biosafety is needed to set policy in this area, which requires research: There is a need for *procedural studies* (such as the proper protocols to inactivate anthrax spores, which equipment works best for a given protocol, which personal protective equipment [PPE] works best to protect the laboratory worker); *behavioral studies* (how best to instill a safety culture in the laboratory; what is the best training material for each skill level of scientist; how can laboratories be inspected in such a way as to be supportive and improve safety over time; how to promote safe practices in routinized biological laboratory environments); and *comparative studies* (to determine the safety level for different laboratory practices, engineering, laboratory set-ups, and equipment).

- **Biological research has become democratized, but biosafety training has not. The US government needs to expand biosafety training and access to biosafety advice to the people who require it.**

Typically, laboratory skills including biosafety are developed over years of training and mentorship in biological research laboratories. Yet, with the advent of new biotechnologies that are relatively inexpensive and able to be pursued outside of a traditional laboratory, more people have begun to do biology research, including amateurs: There is an active, international DIY Bio movement. There have been some outreach programs set up to bring biosafety training to these new practitioners. Community laboratories, a source for education programs, have safety requirements, and there is an "ask a biosafety expert" program freely available on the DIY Bio website. But much more is needed, and as the technologies get more powerful, this problem is likely only to expand.

CRISPR, the revolutionary new gene editing tool, is available to amateurs all over the world in a kit that costs less than $150. There is a pressing need to adapt biosafety training so that the people who need safety advice have an opportunity to receive it. There are also security benefits for reaching out into the communities where this work is performed; the FBI has taken this approach in the WMD Directorate to institute a "see something, say something" campaign for biologists.

- **Laboratory accidents with highly transmissible agents anywhere in the world have the potential to become a public health emergency of international concern. The United States should work toward international norms for biosafety so that all nations appropriately oversee, fund, and train to prevent accidents where possible and mitigate when necessary.**

Most accidents in biocontainment laboratories are limited to the researchers involved and possibly their close contacts. While these accidents are unfortunate events that may have severe consequences for those who are affected, they would not typically become matters of national or international concern. However, laboratory-acquired infections with particularly transmissible pathogens could have consequences that go well beyond the laboratory, beyond borders, and would constitute a threat to national and global security. Consequential laboratory accidents have happened before, but thankfully with limited impacts on international human health: For example, in 2003-04, there were multiple laboratory-acquired infections with the SARS virus, but a quick response halted transmission before the virus could spread widely.

There is a great deal of technical guidance for researchers and institutions to achieve high levels of safety, to train workers, and to foster a laboratory environment that holds safety as a priority. However, national-level biosafety norms could provide reassurance to other nations that research with highly transmissible pathogens is performed with appropriate and sufficient safety systems. It is almost certain that such norms would develop in the aftermath of a laboratory accident, so these commonsense measures should be put in place now. For example, it would be helpful to know that all such research is taking place in countries where there are national standards for the work, including for equipment maintenance, worker safety training, health monitoring, surveillance, and other myriad activities to help keep the

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researchers and the larger public safe, and that the nation has an adequate surveillance system in place to identify and limit potential outbreaks that could result from such accidents.

Without national-level standards and expectations for biosafety, there will remain insufficient incentives to commit the resources required to achieve high levels of biosafety in individual laboratories and institutions. Absent biosafety norms, the United States will not have confidence that all necessary steps are being taken in other nations to prevent a high-consequence laboratory accident from occurring, or to limit its consequences.

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WHEN THE NEXT DISEASE STRIKES: HOW TO COMMUNICATE (AND HOW NOT TO)

IN AN INCREASINGLY INTERCONNECTED WORLD, the potential for infectious diseases to spread internationally is an inescapable fact. The country will face one or more infectious disease health threats over the course of the next administration. Dealing with these threats will require science-based assessment, judicious management, and effective risk communication.

Over the past 8 years, a number of health threats have affected the United States, and public officials have struggled to communicate effectively. During the 2014 Ebola outbreak, some depictions of the threat Ebola posed to the United States caused the public to become much more concerned about the disease than was called for (only 2 people were infected on US soil and both were healthcare workers in direct contact with a patient). During the 2016 Zika threat, we've seen that people have a mixed understanding of the disease and the protective actions they should take, despite months of efforts to inform them. The incoming Administration and Congress will be called on to communicate with the public during similar periods of crisis, potentially ranging from naturally occurring disease outbreaks to intentional bioterrorism, in the future.

Why Is Risk Communication Important?

No matter how effective the planned response, poor communication with the public will greatly undermine its effectiveness. In fact, poor communication could exacerbate the threat and lead to greater disease effects as well as loss of trust in the government's ability to protect the nation in the future. Even a small crisis can spiral out of control without appropriate risk communication, and effective risk communication during a significant event could have a large life-or-death impact.

Failure to communicate well may lead to the perception that the government is unable to respond to the outbreak. For instance, poor communication during Hurricane Katrina led to avoidable deaths, exacerbation of existing racial tensions, and loss of faith in government at all levels. In contrast, using communication practices that have been proven to be effective sets the stage for effective crisis management and helps the public act in ways that help themselves and their neighbors emerge from a crisis. For example, during the H1N1 outbreak, a trusted and reliable spokesperson communicated well about what was known, what was unknown, and what people should do to protect themselves. These messages were well received.

Key Principles in Effective Communication

Public health agencies have increasingly embraced risk communication as an important aspect of emergency response and have expanded efforts to improve the effectiveness of their efforts. For instance, the Centers for Disease Control and Prevention (CDC) have adopted Crisis and Emergency Risk Communication (CERC) practices as central to their response, which stress that successful communication is the first source of information, is accurate, is credible, shows empathy, promotes action, and shows respect.[1]

There are many different descriptions of basic risk communication principles, but they all have a number of concepts in common, including the ability to adapt to a changing situation, understanding the audience, and building trust. Risk communication should be done with the goal of helping people become informed about a potential risk so that they can make appropriate decisions to protect their health, understand response activities, and potentially assist in community efforts to address the risk. Good risk communication practices take into account individual and community knowledge, attitudes, and risk perception and tailor messages to ensure that people are informed about and given concrete steps to protect themselves from infectious diseases.

Aspects of Risk Perception

Regardless of measured and quantitative or technical risk assessment, several factors can make health threats seem

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more "risky" to the public. Risks that are unknown—meaning they are not observable, unknown to those exposed, delayed in effect, new, or unknown to science—and risks that are highly dreaded—meaning they are uncontrollable, catastrophic, fatal, not equitable, high risk to future generations, not easily reduced, increasing in risk, or involuntary—are perceived to be more severe.[2] For instance, people often perceive nuclear energy to be very high risk, but they do not assign similarly high risks to the consumption of alcoholic beverages, even though actual risks from nuclear energy are comparatively very low. However, people are much more familiar with alcoholic beverages, which have a more immediate effect, are controllable, and are voluntarily ingested. In contrast, nuclear power could potentially present risks from radiation that are delayed, unobservable, uncontrollable, involuntary, catastrophic, fatal, and dangerous to future generations. As a result, the latter is perceived to be higher risk than the former. In essence, public outrage plays an important role in risk perception.[3]

When communicating about health threats, officials should be aware of these factors and understand how they will influence the public's reaction. For example, although the intense public reaction to Ebola in the United States was not warranted, considering the specific conditions required for spread of the disease, the fatal and dreaded nature of the disease increased perception of risk. In the case of Zika, the disease can have severe impacts on unborn fetuses, which increases public perception of risk from the disease. Heightened perceptions of risk, regardless of their basis in real risks to the public, need to be accepted as valid concerns to be addressed.

Recommendations

- **Don't be taken by surprise.**

Expect to respond to and communicate about infectious disease threats during this coming Administration. The American public will expect the government to be prepared to have an effective response when such an event occurs, whether it is a bioterrorist attack or a naturally occurring pandemic, and to communicate rapidly and transparently about it. This means that the government will need to provide timely information about what is being done and what is known and not known. A number of widely accepted steps are currently being done, such as maintaining situational awareness about infectious diseases that may spread to the United States, preparing easily modifiable message templates for both intentionally caused and naturally occurring events, and identifying and training spokespeople who are comfortable relaying complex information effectively. Furthermore, establishing an advisory panel ahead of time of people with in-depth understanding of infectious disease and public health practices may help policymakers determine the most appropriate public health response in an emergency.

- **Communicate uncertainty when it exists.**

It is impossible to know exactly how an infectious disease health crisis will unfold, especially in the event of a new or deliberate release of an infectious agent. Communication that is overly certain and then is perceived as "wrong" can significantly undermine public trust and the likelihood that future messages will be accepted and acted upon. Past experience has shown that being clear about what is unknown, what work is still being done to increase understanding, and that information may change helps increase acceptance of messages.

- **Take a deep breath: Carefully consider and communicate policy responses.**

During the next infectious disease health threat, many policymakers, the public, and the media will expect rapid response. However, first impulses for response often require more measured consideration to ensure that they will actually protect health. For instance, it is best to use travel bans, quarantines, and school closures sparingly. Although these sound like effective measures, second and third order effects often undermine them to the point of causing more harm than good. Communicating these complicated relationships will be important to response efforts. Transparent communication about what is being done to determine the best path forward can help to relieve some of the pressure that may lead to choosing a suboptimal response.

- **Eliminate the phrase "out of an abundance of caution."**

Use of this phrase can be a prime indicator that a certain activity isn't warranted by science. What is being communicated is that a certain action may not be necessary but is going to be done anyway just to be overly careful. However, this assumes that there are no consequences for overly cautious and unnecessary actions. In fact, there are consequences to some public health actions that have been taken in epidemic crises—beyond the economic costs, there can be restrictions on civil liberties and loss of resources. In addition, use of this phrase and the activities that go along with it can undermine messages about risks being based in science and fact, and they could suggest to the public that they shouldn't trust science and official recommendations. Instead, a transparent approach that remains consistent and honest about potential risks is needed.

- **Do more research on what works.**

CDC and a number of other federal agencies do high-quality research on existing communication practices and have

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greatly improved risk communication by the federal government. This work has improved the research, practice, and training base for risk communication, but gaps remain. Improvements in risk communication need to be maintained through continual preparation and research; otherwise, progress and expertise will be lost. Furthermore, continued efforts to improve knowledge and practice surrounding what makes up good risk communication are needed.

Continued efforts to develop communication research and products at the federal agency level are important to enabling an effective response to the next infectious disease threat. This not only improves federal communication during infectious disease emergencies, but also results in guidance and best practices that are shared with state and local agencies to improve response at the source.

Conclusion

Effective risk communication is essential in response to infectious disease health threats. These types of threats will affect the next Administration, which will need to have made a number of key investments to respond effectively. Among these investments are appropriate funding for communication efforts at CDC and others at the federal agency level and in state and local governments. In addition, the next Administration should embrace a number of communication practices, including being explicit about uncertainty and avoiding the use of the phrase "out of an abundance of caution."

Furthermore, public health response activities should be carefully considered and transparently communicated with end goals in mind. The stakes of effective risk communication are high. Successful communication and response during the next infectious disease health threat will be important in ensuring public faith and trust that the next Administration can effectively manage threats to the country. Getting risk communication right during the next disease threat will protect the lives of Americans and help to establish the ability of the next Administration to lead effectively during crisis.

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MAINTAINING US LEADERSHIP IN EMERGING BIOTECHNOLOGIES TO GROW THE ECONOMY OF THE FUTURE

ACCORDING TO THE US National Bioeconomy Blueprint (2012), applications emerging from synthetic biology and other biotechnologies "can allow Americans to live longer, healthier lives, reduce our dependence on oil, address environmental challenges, transform manufacturing processes, and increase the productivity and scope of the agricultural sector while growing new jobs and industries."[1(p1)] In addition to benefits to these diverse aspects of American life, biotechnology's potential effect on growing the economy is thought to be immense. Synthetic biology, a technical area that aims to make biology more useful and easier to engineer, is a top 10 key technology for the 21st century, according to the World Economic Forum. BCC Research, a market analysis company, expects the synthetic biology market to grow rapidly from $2.7 billion in 2013 to $11.8 billion in 2018, with a compound annual growth rate of 34.4% over a 5-year period from 2013 to 2018.

Other nations have taken note of the potential for biotechnology to fuel their economic development and have invested accordingly, particularly the UK and China. At the same time that these technologies are seen as a lucrative area for investment by nations, there are increasing concerns that the United States is falling behind in science generally, and that the STEM (science, technology, engineering, and mathematics) workforce is declining. The National Institutes of Health has warned of an "erosion of the competitive position of the US life sciences industry over the past decade." China will overtake the United States in R&D spending by 2020 and has already exceeded the number of doctoral degrees awarded in the life sciences in the United States. The US is currently the leader in synthetic biology and other biotechnologies—but for how long this will remain the case is in question.

A forewarning of the US biotechnology future can be seen in the iGEM (internationally genetically engineered machines) synthetic biology competition. This international competition, which is similar in scope to better-known robotics competitions, started as a class at MIT in 2003. By 2016, it had grown into a premier competition for synthetic biology, with 5,200 participants, spanning 42 countries. It is notable that none of this year's trophy winners hailed from the United States: The winners came from the UK, Australia, China, the Netherlands, Germany, and Taiwan. According to a committee assembled by MIT, the US teams have suffered for years from a lack of laboratory and institutional support.

This trend of decline must be reversed. If the United States is not a leader in the newest areas of biotechnology like synthetic biology, it will lose out on the economic, biomedical, agricultural, and manufacturing benefits that are widely expected to ensue. Given the potential that these technologies could also be used for harm, it would also lose out on opportunities to shape the field as well as to use it for the nation's defense.

Recommendations

- **The US should remain competitive in S&T, including in synthetic biology.**

Maintaining competitiveness in science and technology (S&T), including synthetic biology, involves following a well-known playbook to which the US government should adhere: The United States should fund basic research with minimal fluctuations from year to year; fund STEM education initiatives; institute financial incentives to discourage synthetic biology companies and other biotechnology companies from locating offshore; develop the workforce through training programs; ensure that women are targeted for advancement in STEM fields; and encourage foreign students who receive their PhDs in the United States in technical areas to stay in the country, by issuing green cards enabling them to work here. Targeted initiatives to make the United States an innovative space for science and scientific research generally will help the United States maintain its leadership position across the S&T spectrum, including in synthetic biology. Specific to US leadership in

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synthetic biology, the nation should invest in the scientists of the future and give more support to university iGEM teams to help them succeed.

- **The United States should continue to support a regulatory philosophy that focuses on the end product, which has proven beneficial to innovation, and not a "precautionary" European model. Although there is mounting sentiment against genetically modified organisms (GMO) in the United States, which is counterproductive to US excellence in biotechnology, the regulatory system for biotechnology in this country should continue to be based on sound science, and should not be politically driven.**

The US approach to regulating biotechnology differs from that typically embraced in Europe. In the United States, it is the *product* that needs to be subject to a safety determination, not the process used to *make* a product. This encourages innovation, to come up with better methods to reach the same desired result. European regulatory systems generally adhere to the "precautionary principle," which places the burden of proof on the developer of a product to show that the process used to make a product is not harmful. While precaution in the face of unknown risks sounds like a reasonable approach—it is the essence of the expression "look before you leap"—in practice, it has often resulted in inaction and has discouraged innovation.

The divergence of a precautionary and more typically American pro-actionary regulatory philosophy is evident in the debate about GMOs. In the United States, whether a product is made through GMOs or another method, it is the end-product that is regulated. In Europe, the act of genetically modifying organisms is severely restricted and under tight regulatory control. As synthetic biology has been termed "genetic engineering on steroids," the current US regulatory approach is more favorable to synthetic biology development and should be maintained even if there is pressure from anti-GMO activists. The United States is in the midst of updating its Coordinated Framework for Regulating Biotechnology Products—that is, the division of responsibilities among the Environmental Protection Agency, the US Department of Agriculture (USDA), and the FDA, which all have oversight responsibilities for biotechnology products—and should maintain a system that is based on science.

- **The United States should ensure that products made in synthetic biology are appropriately regulated and overseen.**

The US regulatory system for biotechnology products should be driven by science and, importantly, should not have gaps that may sow public distrust in the regulatory oversight. The US regulatory system needs to be well-equipped to assess the risks associated with future biotechnology products, particularly as synthetic biology is likely to increase the gaps in regulation. As one example, a 2013 fundraising campaign on Kickstarter alarmed experts by promising to produce glowing plants and distributing their seeds for planting (in the end, the technical obstacles were too great, and the company was not able to deliver this product). The activities were not forbidden under any regulation, though many reasonably thought this would be an activity that should be subject to regulation.

The regulatory framework is being updated, and this process should continue through the next Administration. The last time the framework was updated was in 1992, a very long time ago in terms of biotechnology development. An outdated regulatory framework leads to confusion about who regulates what, and whether some products are indeed subject to regulation, which leads to a loss of public confidence in biotechnology products. It benefits everyone to have a clear and coherent regulatory system: consumers and developers, and the American public.

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International Engagement Is Critical to Fighting Epidemics

In the past 15 years, a series of infectious disease emergencies—the anthrax attacks in 2001, the rapid global spread of severe acute respiratory syndrome (SARS) in 2003, the 2009 influenza A (H1N1) pandemic, the emergence and international spread of the Middle East respiratory syndrome coronavirus (MERS-CoV), the largest Ebola epidemic on record, and the emergence and spread of Zika virus—have increased global political concerns about emerging infectious disease threats and deliberate epidemics. Among these events, Ebola and Zika serve as stark reminders that, if left unchecked, infectious disease outbreaks that originate in one country can produce profound international human, political, and economic consequences. Limited public health and healthcare infrastructure in West Africa quickly enabled Ebola to rapidly spread to multiple countries, resulting in unprecedented levels of illness and death. The suffering caused by the epidemic led to social unrest and economic distress that threatened to undermine decades of US investment aimed at bringing political stability to the region. To help end the epidemic, the US Congress appropriated more than $5 billion in emergency funds.

Although it was first identified in Uganda in 1947, global concerns about Zika virus accelerated last year when Brazil announced an association between Zika virus infection and a birth defect known as microcephaly. To date, Zika infections have been reported by 69 countries, including the United States, which has identified more than 37,000 cases (including territories).[1] The costs associated with this crisis have been staggering. The World Bank estimates that the short-term economic impact of Zika in Latin America and the Caribbean will be upwards of $3.5 billion.[2] Though estimates of the short- and long-term economic impacts on the United States are not available, the CDC has estimated that it may cost up to $10 million to provide long-term care for each child who is born with Zika-associated birth defects.[3]

What we have learned from such events is that there are consequences in the United States and other countries when the nations that first encounter an outbreak lack adequate public health infrastructure to detect and respond to acute infectious disease events. When countries are unable to recognize and contain outbreaks, it increases the risk that the diseases will quickly move beyond their borders. The more a disease spreads beyond its source, the harder and more costly it is to contain. This holds true for both natural epidemics and biological attacks.

The increasing recognition that any significant infectious disease outbreak occurring abroad may pose a threat to America has prompted the United States to work with other nations to bolster their response to public health emergencies as a means of protecting national security. Over the past 15 years, US leadership has been important in ensuring the success of a number of international initiatives aimed at improving global health security, and, moving forward, the United States should continue to build on progress made to date. Specifically, it is in the best interest of the United States to pursue as a matter of priority the international initiatives discussed below.

Recommendations

- **Maintain momentum for the International Health Regulations and the Global Health Security Agenda.**

Following global missteps in controlling the spread of the SARS virus in 2003, the 2005 World Health Assembly adopted revisions to the International Health Regulations (IHR) with the aim of improving national and international efforts to detect and respond to events like SARS and other public health emergencies of international concern. The revised IHR outline specific minimum core public health capacities and implementation processes that nations need to adequately address acute public health threats. Although 194 states parties signed onto this legally binding treaty, progress toward implementation of the IHR has been very slow. The initial target for full IHR implementation was 2012; however, even by 2014, only 33% of nations indicated that they had successfully implemented these minimum requirements.[4]

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To jumpstart stalled progress toward implementation of the IHR, the Global Health Security Agenda (GHSA) was established in 2014 with the goal of increasing national government support for IHR implementation and fostering a multilateral and multisectoral approach to developing health security capacity. Currently consisting of more than 50 countries, and with support from intergovernmental organizations (IGOs) and nongovernmental organizations (NGOs), the GHSA provides support for nations to assess their existing health security capabilities, identify gaps, and formulate plans to fully implement the IHR to ensure domestic and international capacity to detect, prevent, and respond to health security threats. One of the driving principles of the GHSA is building interagency coordination at the national level, and particularly improving the links between health and security authorities, to facilitate information sharing and improve response to a wide range of biological events, including the deliberate use of dangerous pathogens.

US leadership through the GHSA has breathed new life into the IHR, drawing much-needed awareness from national governments and providing a multilateral mechanism to provide support to low-resource nations. In 2015, the United States committed to contribute more than $1 billion to the GHSA—with more than half of those resources designated for African nations. Other G-7 nations followed the United States's example and pledged contributions to provide support to a total of more than 60 countries.[5] The United States has also worked with GHSA partner countries and the WHO to develop a tool for conducting external assessments of countries' baseline health security capacity. The WHO's IHR Joint External Evaluation (JEE) tool builds on the GHSA's focus areas to provide a standard metric by which countries can assess their current baseline capacities and measure future progress toward full development of IHR capabilities.[6]

The WHO currently has a list of dozens of nations who have volunteered to complete formal JEEs—a welcome development. After more than a decade of stalled progress on IHR implementation, it is encouraging to see a new wave of enthusiasm for global health security. To sustain and build on this momentum, the United States must continue to work with the WHO and other GHSA partners to assist countries in assessing their health security capacity and making the necessary improvements to ensure that epidemics no longer pose significant threats to society. This will require continued financial and technical support from the United States for the GHSA and the WHO. US leadership on both of these fronts has been essential to building momentum for the GHSA and the IHR, and it will be vital to expanding the success of this program to bolster both global and domestic health security.

- **Promote evidence-based plans for limiting international spread of disease.**

The absence of evidence-based plans—both in the United States and abroad—for limiting the spread of disease continues to hinder global response to outbreaks. During the Ebola epidemic in West Africa, there were contentious debates in the United States over whether and how to implement disease control measures at national borders and points of entry. After the importation of a single case of Ebola by a traveler from West Africa, political leaders called for a ban on commercial travel from West Africa and mandatory quarantine for all healthcare workers returning from the region. Health authorities, including the WHO and CDC, deemed that travel bans would cause more harm than good and cautioned strongly against them. Additionally, some states defied CDC recommendations regarding returning traveler assessment and monitoring and implemented mandatory quarantines and movement restrictions on travelers from West Africa.

National leaders should take a strong stand against the imposition of non–evidence-based measures to control the spread of disease. Past experience has shown that when countries employ public health measures such as quarantine and travel restrictions when they are not likely to be effective, they may exacerbate the toll of the outbreak. For example, during the West Africa Ebola epidemic, there were many calls for the United States to ban travel from affected countries—including some from high-ranking members of Congress.[7] As commercial airlines began voluntarily canceling flights to and from the affected countries, reports surfaced of medical personnel and supplies experiencing inordinate delays getting to West Africa. At a time when clinical care and supplies—particularly personal protective equipment—were in critically low supply, these delays likely contributed to countless additional deaths and actually caused further spread of the disease rather than mitigating it.[8,9]

In future outbreaks, the United States would be in a better position to deter other countries from taking harmful actions—such as the unwarranted detainment of American airline passengers and other unnecessary restrictions on travel and trade—if we openly commit to employ in the United States only those measures that are based on scientific evidence. Measures such as quarantine, point-of-entry screening, and traveler monitoring should be implemented only when there is reasonable evidence that they will be effective. Additionally, the United States should lead by example by developing domestic plans for containing the spread of disease that have the strong backing of scientific evidence.

Countries that restrict travel during infectious disease events without scientific justification do so without the backing of international law. The core goal of the IHR—the legal framework that articulates how nations, including the United States, should respond to international disease threats—is to "prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."[10] The IHR

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explicitly discourage the use of public health measures for which scientific evidence is lacking.

➢ **Seek international consensus on data sharing.**

Though recent changes to the IHR have improved the timeliness with which countries report potential public health emergencies of international concern to WHO, there continues to be a lack of consensus regarding whether and how countries should collect and share other data that are needed to inform management of outbreaks. Recently, WHO has worked with countries to address some of these concerns by developing the Pandemic Influenza Plan (PIP) to guide the sharing of influenza specimens and isolates, which are needed to understand the changing epidemiology of influenza outbreaks and to inform vaccine and diagnostic development efforts. However, the plan does not establish a global consensus for how countries, NGOs, IGOs, academics, and private companies (eg, pharmaceutical and biotech sectors) should collect and share surveillance information and collaborate on research in the midst of acute infectious disease emergencies. Sharing data and samples is essential because the availability of accurate, reliable, timely data drives the ability to investigate and respond to infectious disease events and is vital to informing public health control measures and for supporting efforts to develop and test new pharmaceuticals. Considering rapid advancements in public health informatics and biomedical research, the United States should work with WHO and its international partners to develop and adopt an international consensus framework of best practices to guide collaborative research during outbreaks, regardless of the pathogen.

Conclusion

A number of recent events have highlighted the threat of the continued emergence and spread of epidemic diseases. While the vast majority of these threats begin abroad, increased globalization has ensured that these diseases are merely a flight away. The United States, through international mechanisms such as the GHSA, can provide support for other nations to implement surveillance, preparedness, and response capacity for natural, accidental, and deliberate threats. With these systems in place globally, these types of events can be identified rapidly and contained using national or regional response assets. International cooperation to share data and biological material can support rapid investigations and pharmaceutical development to limit the global impact of emerging diseases, and international standards for evidence-based public health and medical interventions will ensure that responses are managed effectively with minimal impact on international trade, travel, and the US and global economies. International engagement is vital to addressing disease threats before they ever reach our borders as well as mitigating their impact on the global economy and health.

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PREVENTION OF THE DEVELOPMENT OR USE OF BIOLOGICAL WEAPONS

PREVENTING THE DEVELOPMENT AND USE OF biological weapons should continue to be a top priority for the nation. There are fundamental issues that make prevention difficult, however. 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, scientific culture collections, and in sick people and animals everywhere. It is now possible to synthesize pathogens from scratch, particularly viruses, with technologies that are inexpensive and globally available. The skills and equipment for making a biological weapon are largely the same as those required for progress in medicine, agriculture, and other fields and are required for future economic prosperity for the nation, so they cannot be locked away. Efforts that might be useful in deterring terrorist groups will be different than those targeted toward nation states—and *every* nation state is presumed to have the technical and financial resources to have a biological weapons program should they choose to embark on one.

In spite of these challenges, the US government has options for increasing the likelihood that biological attacks can be prevented, through 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 security practices for legitimate scientists.

Recommendations

- **The US government should continue to strongly support the Biological Weapons Convention and other international efforts that both prevent terrorism and promote the development of a global public health infrastructure.**

The cornerstone of biological nonproliferation strategies is the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, commonly known as the Biological Weapons Convention (BWC). The BWC is 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 that are highly likely to have offensive biological weapons programs. However, no country openly goes against the international norm to display an offensive biological weapons capability.

This prohibition against biological weapons development should continue to be strengthened with vigorous US 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 Global Health Security Agenda, which focus donor attention on areas where the global public health infrastructure needs to be strengthened, also should be actively promoted by the US government. The devastating Ebola outbreak in Guinea, Sierra Leone, and Liberia that killed 11,310 people in 2014-15 should be seen as a harbinger of what could happen again should public health infrastructure not be maintained throughout the world, and what could easily result from a deliberate bioattack.

- **The United States should strengthen deterrence of biological weapons by expanding our ability to reduce the consequences of such attacks and by increasing investments in surveillance and 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 United States 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

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biological attack. In addition to this form of deterrence, the United States should press ahead with efforts to strengthen its ability to perform rapid surveillance, as well as sophisticated analysis of microbial forensics. 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 United States should increase its support for private sector efforts to screen gene synthesis orders.**

Gene synthesis companies provide services that support medical research, as well as biotechnology and pharmaceutical product development. However, these services could shorten timelines for developing a biological weapon if the genetic material that encodes a pathogen is made to order. In response to this threat, a number of international gene synthesis companies have already formed a compact to screen orders. Their screening exceeds the guidelines put forward by the Department of Health and Human Services in 2010. However, these screening controls are becoming less valuable: Not all companies screen orders, there is a time/money cost advantage that nonadherents to the guidelines benefit from, and screening is becoming more expensive to companies. As the costs to produce genes are dropping, the costs of screening have remained constant, so the screening is becoming more of a burden and inhibitory to the companies' competitiveness.

The US government can do more to support this screening mechanism to preserve this preventative measure in the years ahead. The United States should work to increase the number of companies that perform gene screening, promote awareness of companies' codes of conduct, and encourage providing those companies with a means to report a suspicious order.

Finally, there is a need to research the effectiveness of this preventative measure, and how to improve it, as there are no publicly available data about how valuable the sequence screening is in stopping misuse. It could be that it is customer screening, and not sequence screening, that is the most valuable part of the security screening process, and research should be funded to examine its effectiveness and how best to improve screening.

- **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." These conclusions were echoed by the 2015 Blue Ribbon Study Panel on Biodefense. Making progress will require placing a higher priority on US intelligence collection against biological threats, finding better ways to reward biological 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.

- **US efforts to control legitimate science that may lower barriers to biological weapons development are limited. Nonetheless, an educational and awareness-raising campaign should be part of scientific training.**

Over the past 15 years, the US government has taken numerous actions to prevent legitimate science from lowering barriers to biological weapons development by nefarious actors. The Department of Health and Human Services (HHS) advisory committee, the National Science Advisory Board for Biosecurity (NSABB), defined such dual-use research of concern (DURC) as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." US scientists who work with regulated pathogens are currently required to screen their research for issues related to dual-use research of concern. However, it is hard to know, without extraordinary insight into the minds and plans of nefarious actors, how a particular piece of scientific knowledge may be misused. It is also a challenging process to balance the risks of publication and subsequent misuse along with the potential for a more positive outcome.

It will be difficult to manage the "dual-use" problem without also inappropriately limiting science, with uncertain effects on increasing security. Yet, all scientists should know that their work could be misused, and there should be a process to evaluate such research. For particularly problematic studies, scientists should be able to explain the steps that have been taken to minimize that risk, and to explain the importance of what they are doing.

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