

United States Senate
Committee on Homeland Security and Governmental Affairs

“Ten Years after 9/11 and the Anthrax Attacks: Protecting Against Biological Threats”

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Mr. Chairman, Senator Collins and members of the committee, thank you for the opportunity to speak to you today on the issue of U.S. preparedness for biological threats 10 years after the anthrax attacks.

My name is Tom Inglesby. I am the Director and CEO of the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) and Associate Professor of Medicine at the University of Pittsburgh. The Center for Biosecurity is an independent nonprofit organization of UPMC. Our mission is to strengthen U.S. national security and resilience by reducing dangers posed by epidemics, biothreats, nuclear disasters, and other destabilizing events. Our staff comprises experts in medicine, public health, national security, law, economics, the biological and social sciences, and global health. As you have requested, I will focus my remarks on medical countermeasure development, biosurveillance, and other issues raised in our Center’s recent *Crossroads in Biosecurity* report on the 10 yr anniversary of the anthrax attacks.

I want to thank this Committee for holding hearings such as today’s that focus on protecting the country against biological threats. Pragmatic, informed oversight for challenges of this complexity and importance to national security is essential. In my testimony today, I will include many challenges that we hope will be addressed in the Pandemic and All-Hazards Preparedness Act reauthorization, as well as other biopreparedness priorities.

The potential biological threats to the United States are quite serious. The country could face a new flu pandemic that spreads as efficiently as H1N1 but has case fatality rates like H5N1 or other more lethal strains of flu. It could have to confront a novel virus that jumps from animals to humans, spreads efficiently from person to person, and circles the globe – in the way that the movie *Contagion* recently portrayed.

And the US could have to cope with the use of a biological weapon. The anthrax letters of 2001, tragic and shocking because of the lives lost and people sickened, were only a very small example of a biological weapon. Too many people have taken away from that experience that future bioevents would mirror that one in size and character. While we could see a repeat of the 2001 anthrax letters, biological weapons attacks of the future could be entirely different in character and affect extraordinary numbers of people. In 2009, President Obama’s National Security Council said: “The effective dissemination of a lethal biological agent within an unprotected population could place at risk the lives of hundreds of thousands of people. The unmitigated consequences of such an event could overwhelm our public health capabilities, potentially causing an untold number of deaths. The economic cost could exceed \$1 trillion for

each such incident.” Other reports from our intelligence and national security community as well as reports from an independent commission have consistently said that bioweapons are a serious concern, and probably the most likely WMD to be used against the country.

Since 2001, there has been progress in a number of areas of biopreparedness. We have dedicated biodefense programs in many agencies of governments, and many highly effective civil servants in government working on these issues. For example, CDC has made great strides in its state and local public health preparedness programs, its emergency operations planning, its stewardship of the strategic national stockpile, and its management of laboratory security programs. DHS S&T has brought increasing scientific rigor to many of the difficult scientific and technical challenges in bio-response including the Biorisk assessment, the Material Threat Determinations, and their recently completed standards regarding white powder incidents, which are a major advance. The FDA has been working hard to reform regulatory science, to speed its regulatory review process, to seek innovations or alternatives to the Animal Rule, and, to address challenges of making safe and effective products for children. DOD is evolving its Cooperative Threat Mission, working to get more applied science and innovation into its efforts to produce countermeasures, and helping support the international biosurveillance mission. HHS/ASPR has provided grants for hospital preparedness and has continued efforts to develop and procure medical countermeasures. There have also been many important developments at the state and local level, particularly in the realm of better hospital and public health preparedness.

These efforts and programs have helped us make progress against biosecurity threats. And many of the advances over the last decade have also made us better prepared for natural disasters and accidents. In fact, the majority of the work we do to prepare for biological threats will continue to serve secondary purposes that are vital. Our own study of the most recent federal biosecurity budget showed that 92% of funding for biodefense in fact served secondary additional purposes, such as infectious disease research, hospital preparedness and disaster response.

But clearly we are not yet prepared to cope with the biological threats we could face. There are important issues we need to address in countermeasure development, biosurveillance, public health preparedness and more broadly in biosecurity.

Countermeasure development

One of the core, and most challenging, components of our national defense against biological threats is the development and stockpiling of medical countermeasures that can be given to citizens in the event of a biological attack or significant infectious disease outbreak. Development of novel drugs, vaccines, and diagnostics is expensive, inherently a risky undertaking, and is under-funded in relation to the national security need. Large pharmaceutical companies that have experience in advanced development and regulatory processes are not engaged in the development of medical countermeasures for CBRN threats, because there is not a significant enough commercial market for such products, unlike products for chronic diseases and influenza. While some important advances have been made in countermeasure development over the past 10 years, procurement of new products has been limited to countermeasures addressing influenza and a few biological agents.

In assessing the current status of our countermeasure efforts related to potential bioweapons pathogens, it is important to start with the list of agents identified by the DHS and HHS as presenting the greatest threat to public health. To date, DHS has issued 12 Material Threat Determinations (MTDs) for top priority biological threats to the American public, based on information related to potential public health impact, intelligence and other threat information.

Countermeasures for just three of these threats – anthrax, smallpox, and botulism -- have received the majority of advanced development or procurement funding. Special Reserve Funds have been used to develop and procure anthrax therapeutics and vaccines, a heptavalent botulinum antitoxin, a smallpox vaccine for the immune-compromised, and a smallpox antiviral drug. Although products for some of the other 9 biological threats on the MTD list have received development contracts, they are, by and large, still early in development. The majority of the over 70 products in BARDA's research and development pipeline to counter biological threats are in the early pre-IND or Phase I stage of development. Products in this category of development typically require 8-12 years more of development before licensure, and products at this early stage have a high rate of failure. It is unclear whether new or existing medicines/vaccines for anthrax, smallpox, and botulism will continue to be the focus over the next 5 years, and/or whether BARDA's focus will be on the procurement of products directed at the other 9 biological agents that are material threats.

Given the number of MTDs and the distance that still must be travelled to develop licensed products for them, it would be quite valuable to understand the roadmap for the process ahead. It would be useful to know the extent to which the development of these needed products requires more basic science versus more advanced development? Clearly the funding for the work should be allocated accordingly. Or for some, specific regulatory problems may be the only remaining issue to address, in which case funding for FDA management of those issues should be the priority. This kind of information is not only critical for planning, but would help all those involved in the MCM development process in and out of government to understand how decisions are being made, and what the priorities of the US government are. It would also illustrate how the process is integrated from its start in basic science to the point when products can be procured.

In addition, when decisions are made to purchase a particular medicine or vaccine for the Strategic National Stockpile, a public explanation should be provided that explains the choice of medicine purchased, justifies the quantities, and explains how that countermeasure will be used operationally in time of crisis. It does not make sense to have products in the Stockpile that cannot be used effectively on the ground in the time of crisis. An added level of explanation will serve to protect the process from undue political influence and will help the public health officials understand the tools at hand and how best to use them in the event of a crisis.

BARDA recently released its Strategic Plan for the 2011-2016 timeframe. In the plan, BARDA says that it has "begun to address the development of broad-spectrum antimicrobials and technologies and platforms with multi-use potential." We support this goal, but want to make sure it does not unduly raise expectations about what is feasible. It is increasingly appreciated how challenging it will be to develop drugs, vaccines, and diagnostic tools that keep pace with the extraordinary advances in biotechnology. As a longer term goal, we should be working to move beyond a one-bug/one-drug approach and aspire to develop and obtain broad spectrum,

dual use products and platform technologies. Having a portion of the biosecurity R&D effort oriented toward that goal makes sense. However in the near term, there are few scientists or industry leaders who think this kind of shift will happen any time soon, certainly not within 5 years. In the short term (at least the next 5 years) we will need very applied, very directed development of the specific products necessary to address the greatest material threats to the country. There should be transparent and specific goals for product development that are technologically feasible within the 5 year timeframe and are achievable with our current government infrastructure and private sector partners, and prioritized according to the resources available.

It will also be important in the near term to advance ongoing efforts in government to stretch our limited biosecurity resources in smart and sensible ways. For instance, we support government initiatives to, where possible, extend the shelf life of products in the stockpile, investigate the feasibility of reducing the duration of antibiotic courses for prophylaxis, and complete dose-sparing studies that could lead to the ability to vaccinate more people while also decreasing the costs to the government.

My final point on medical countermeasures has to do with funding. There has not been enough advanced development funding in the budget for this process as compared to the funding allocated for basic science. If a private company had committed to developing the full list of required products that the US government is trying to develop, it would have had to commit billions/yr in advanced development funding. BARDA has received a small fraction of that to develop CBRN countermeasures. It is our understanding that the BioShield Special Reserve funds will run out this year. This fund needs to be replenished if we are to continue to procure products for the stockpile.

FDA was appropriately funded to deal with medical countermeasures for the first time last year. But that program's budget was reduced from \$170M to \$19M in the Senate and \$0 in the House in the recent bills. Experts in and out of the government involved in this work widely agree that regulatory challenges are one of the most serious issues to deal with in the development process. Among other things, FDA is responsible for coming up with alternatives or innovations to the Animal Rule and speeding up the review process. This work would be significantly set back or halted altogether if FDA's budget is reduced by 90% or more.

Beyond any one specific program, the changes in the federal budgeting process over the past year have undermined important programs. Within the federal agencies, long-term program planning is nearly impossible when every year is funded via a continuing resolution. New priorities cannot be established, and course corrections are harder to make. How are agency leaders supposed to responsibly manage programs with the constraints of such a system? And how is the private sector supposed to interact with a government that runs like this? The U.S. government should reestablish a clear, sensible, and predictable budget process for biodefense.

Biosurveillance

There has been a good deal of Administration and Congressional attention paid to improving federal, state and local biosurveillance systems, including a major advisory committee to the

CDC, a current White House strategy effort and many other initiatives. There have been substantial gains made in biosurveillance, but much work remains to be done.

Biosurveillance systems are seeking to look for evidence of new outbreaks, or they are seeking information to better understand or help contain an outbreak. Information is needed to understand what is happening: how many people are already sick; how is the disease spreading; how severe are the cases; who is most at risk? Other information is needed to understand how an epidemic is unfolding and what public health interventions are working. And other key biosurveillance information is key to the response: which treatments are beneficial; what is the supply of vaccines and medicines; and what medical resources are available. Given the breadth of these information needs and the wide range of organizations that require various elements of this information during different time frames, we believe it is infeasible that any single biosurveillance system can satisfy all of these needs.

In many places, biosurveillance systems are still quite rudimentary, and rely on clinicians and laboratories to phone, fax, or mail in reports of important diseases. If public health officials want to obtain additional information, they often must contact hospitals and clinicians one by one. Each of these time-consuming steps is subject to delay, and it can be difficult to keep up in the midst of a large-scale outbreak. We need to modernize our biosurveillance tools in the following ways.

Electronic Reporting

A major boost for biosurveillance could come from improving public health officials' access to data from healthcare providers, but the ongoing initiative to promote the use of Electronic Health Records (EHRs) across the nation does not adequately address the importance of these data for biosurveillance.

HHS has created a number of criteria for providers to meet in order to receive incentive payments for using EHRs – effectively conveying useful data to public health agencies for biosurveillance purposes is not one of those criteria. In addition, there is no funding for already cash-strapped health departments to allow them to develop data systems to receive incoming EHR data and convert it into actionable biosurveillance information. More than \$18 billion in federal funds has been allocated for incentive payments for healthcare providers to promote adoption of EHRs. A very modest portion of these funds should be used to support health departments to enable them to receive and analyze EHR information from providers in order to detect and manage significant outbreaks. If public health continues without this modern capability, then transmission of data from providers to public health offices is almost meaningless.

If you poll many public health officials, they will consistently cite how important electronic laboratory reporting is to their surveillance work. Laboratory information often provides the most precise and reliable information about a new case of illness, and sometimes the earliest information. If an anthrax, plague, or botulism outbreak were to occur, it would be very difficult to get basic information from laboratories that could tell us how many people are infected or how widespread or severe the outbreak is. While electronic lab reporting does occur in some labs,

particularly in public health labs, it is not uniformly done in the private sector labs which do most of the diagnostic testing overall in the country. Given how important this information is, we need to set a path to ensuring that all notifiable diseases are automatically and immediately reported from the lab to the responsible public health department and continue to be transmitted throughout the course of an outbreak

Diagnostics

Another pressing need in surveillance is the development of technologies to improve the accuracy and speed with which we diagnose sick people. Rapid diagnostics are our best hope for detecting outbreaks early. Although 10 years have elapsed since the anthrax attacks, the diagnosis of this deadly disease is still dependent on assessing a patient's symptoms (which can be imprecise) and/or by growing clinical specimens in the laboratory (which is time-consuming). Rapid, reliable, and cheap diagnostic tests for a range of diseases are within reach, but development is slow, and commercialization is difficult due to high costs, market failures, and other factors. Although U.S. agencies such as BARDA are authorized to develop and purchase the diagnostic tools that will be necessary to manage public health emergencies, progress in this area has been limited. The USG should address this critical gap in our biosurveillance capabilities by making the development and acquisition of diagnostic tools a higher priority.

Data Integration

We also need to do better job combining public health surveillance information with other sources of information that exists in other sectors – such as law enforcement, intelligence or private sector logistical or commercial information. This information resides in federal agencies, state and local agencies and in the private sector. During the 2011 *E. coli* outbreak in Europe and the 2008 Salmonella outbreak in the U.S., it was private sector supply chain and shipping data that proved most useful in identifying the contaminated sources responsible for those foodborne outbreaks. Congress tried to address this problem in 2007 with passage of the “Implementing the Recommendations of the 9/11 Commission” bill, which called on DHS to develop a National Biosurveillance Integration Center (NBIC) to coordinate biosurveillance across the federal government. Though there have been many delays and mis-steps, NBIS has new leadership and has the potential to make real strides on this problem. It would be more effective to work to improve the functioning of NBIS than to give up on the effort. If NBIS does not address it, we will just have to come up with another approach to integration of information.

Public Health Preparedness

In the decade since 2001, many more laboratories have been built and are equipped to test for important diseases. State health departments have hired more epidemiologists to review, investigate, and interpret disease reports, and public health departments are able to maintain 24/7 monitoring capabilities. Prior to the anthrax letters, it was difficult for health departments to detect and conduct surveillance for new viruses, as most lacked even the most basic of surveillance infrastructure and personnel. Preparedness funding greatly strengthened these efforts, so that, for example, when the 2009 H1N1 influenza pandemic was discovered, health departments were able to start performing surveillance for new cases using CDC test kits within

days. As health departments have built this capacity to respond to biological threats, they have found these programs quite valuable in preparing for and responding to other disasters.

Recent declines in both federal preparedness funding and state and local financial resources are directly threatening these gains. Federal funding for state and local public health preparedness programs has declined by 27% since 2005 with a cut of more than \$100M since FY2010 alone. That loss, combined with state budget cuts due to the economic downturn, has made it difficult for health departments to maintain newly developed information systems and analytical staff.

Significant personnel losses – including trained epidemiologists-- have resulted in reduced capacity, including emergency preparedness capacity, in 40% of public health departments nationwide. There are 44,000 fewer persons working in state and local health departments than there were 2 years ago. There are many examples of the value of CDC funded state and local health department preparedness efforts, not just for biological threats, but for other kinds of responses as well. The Vermont Department of Health (VDH), with the support of CDC preparedness funding and the Career Epidemiology Field Officer program, has been critical in responding to the release of radioactive materials at the Vermont Yankee nuclear power station this year. In response to devastating flooding in the Midwest, the North Dakota Department of Health assisted in the evacuation of thousands of citizens and led the evacuation of hundreds from vulnerable healthcare facilities. The department pre-deployed medical sheltering for up to 700 evacuated patients and mobilized medical volunteers. In 2008, Kentucky received over 1,500 evacuees from Hurricane Gustav who were victims from the coast, and the Kentucky Department for Public Health supported the medical needs of evacuees. The New Jersey Department of Public Health responded in 2011 to one of the most devastating natural disasters to impact the state, Hurricane Irene, working double and triple shifts to provide care to the more than 3,500 evacuees and victims, including those from over 40 healthcare facilities.

If the proposed cuts take place in this year's CDC preparedness budget, preparedness efforts like those will be threatened. As many as 1,500 front-line state and local public health professionals would need to be eliminated. The cuts would degrade national capability for disease detection, monitoring, and real-time situation awareness -- this capability was essential in responding to H1N1.

The cuts would also eliminate CDC's ability to prepare for nuclear or radiological terrorism, to include assisting state/local health departments with radiological exposure, contamination assessments, field investigations and advice on protective actions related to direct/indirect human and animal exposures. They would diminish the capacity of CDC's diagnostic program for emerging diseases; the chemical laboratory and response programs; the Epidemiology and Response Branch; and, the Laboratory Response Network. And the cuts would eliminate all funding for the academic Centers for Public Health Preparedness which is the only CDC external funding for academic research that focuses on improving preparedness. For all these reasons, I would urge Congress to reverse these cuts to CDC funding.

Additional priorities

Hospital preparedness

Prior to 2001, there were few dedicated hospital preparedness efforts. Preparing hospitals to respond to disasters was often a vocational after-hours pursuit. The preparedness standards of the Joint Commission (the entity that accredits most U.S. hospitals) were minimal at the time and there was very little in the way of federal or state guidance or funding. Following the 9/11 attacks and the anthrax letters, hospital preparedness greatly improved due in large part to the Hospital Preparedness Program (HPP) in HHS/ASPR and the upgrading of the Joint Commission's preparedness standards.

My colleagues at the Center documented this improvement in a nationwide study published in 2009. We found that in addition to significant improvement in preparedness of individual hospitals, collaboration among hospitals and between hospitals and local and state government agencies had greatly improved. We found that in many locations, hospitals and agencies had created formal or informal coalitions to address healthcare preparedness and response. The benefit of these coalitions has been demonstrated in a number of recent events, including the Virginia Tech mass shooting, the Minnesota bridge collapse and the 2009 H1N1 influenza pandemic.

Although preparedness has improved at most hospitals in ways that should improve resilience to more common disasters, such as tornados, multiple victim shootings, fires, etc, we found progress limited in efforts to prepare for catastrophic health events—a disaster that would result in many thousands of patients. Examples of such an event would include wide-area bioterrorism, a nuclear detonation and a large earthquake. Neither hospitals, local jurisdictions, states nor the federal government have realistic plans for how the medical needs of this many people could be adequately addressed.

The federal National Disaster Medical System (NDMS), which has been valuable in responding to many crises, would have limited capacity to respond to the events of a catastrophic health event. Collectively, all of the deployable medical resources of NDMS would be insufficient for the response. Many patients would need to be transported to private hospitals around the country. NDMS has contracts with thousand of hospitals for this purpose and depends primarily on the U.S. Air Force to transport patients over long distances. However, the military's capacity to move patients is limited and takes considerable time to ramp up. There is not currently a feasible plan regarding how to move large numbers of patients to other areas of the country for care. The role and capacity of NDMS in such a catastrophe should be reexamined, including its deployable teams, its transportation capacity and its definitive care (hospital) component. In addition, HHS will need greater involvement of the private sector to enable an effective response on this scale.

Decontamination

In 2001, government buildings and media offices contaminated by anthrax spores were remediated to the highest possible standard—to the point at which zero viable anthrax spores

could be detected. The process was thorough but costly and slow. It would be impossible to replicate following a wide-area attack.

Because there are few historical examples of aerosolized releases, we have limited information regarding the level of infectivity and aerosol dynamics of anthrax spores deposited on surfaces. We don't know how likely *B. anthracis* spores are to cause disease in humans after re-suspension, and we do know the probability of re-suspension can differ depending on surface (i.e., concrete, carpet, vegetation, etc.) and climate. Health risk is especially uncertain when it comes to outdoor environments. We need to know if the 2001 standard of zero viable spores is necessary, or if there is a less rigid standard that is reasonable and acceptable. There are some research efforts underway to examine these issues, and these should be supported and encouraged.

In addition to scientific research, there are a number of things that the federal government can do to improve our remediation capabilities. We need to ensure sufficient laboratory resources - remediation after an anthrax attack will begin and end in the laboratory. The necessary labs must have the resources and capabilities to deal with this kind of event.

Conclusions

The country has made steady progress in the last decade, but there is much more that needs to be done to make us resilient to biological threats. There is vitally important work to do in countermeasure development, public health preparedness, biosurveillance and other key issues in the years ahead. We hope that the coming reauthorization of the Pandemic and All-Hazards Preparedness Act will address many of the issues that I have outlined today. Thank you for this opportunity to provide recommendations in each of these areas.