

**United States House of Representatives  
Committee on Homeland Security  
Subcommittee on Emergency Preparedness, Response, and Communications**

***“Bioterrorism: Assessing the Threat”***

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Madame Chairman, Ranking member Payne, and members of the subcommittee, thank you for the chance to speak to you today on issues regarding the threat of bioterrorism.

My name is Tom Inglesby. I am the Director and CEO of the UPMC Center for Health Security of the University of Pittsburgh Medical Center (UPMC) and Associate Professor of Medicine and Public Health at the University of Pittsburgh. I’m an infectious disease physician by training.

The Center for Health Security is an independent, nonprofit organization of UPMC. Our center’s mission is to protect people from the consequences of epidemics and disasters and to build resilience in communities against these challenges. My colleagues and I have been working on issues related to preparedness for bioterrorism and other major threats for the last 15 years.

There are a number of major biological threats that confront the nation. Among these are the rising levels of antimicrobial resistance in American hospitals leading to increasing numbers of untreatable infections; the prospect of new pandemics of influenza or other novel emerging infections like SARS or MERS; the possibility of a laboratory accident in which engineered contagious pathogens cause epidemic disease; and, of course the issue prompting today’s hearing, the potential for the use of biological weapons in acts of terrorism. There are many commonalities between bioterrorism and these other biological threats, and there are also aspects of the bioterrorism threat that require specific, major planning and action.

My three main messages for the committee are the following:

- The capability to create and use biological weapons exists widely in the world.
- The consequences of the use of such weapons could be substantial loss of life and societal disruption.
- While substantial progress has been made in past years, there is a great deal that needs to be done to prepare to respond to bioterrorism.

I’ll elaborate on these messages in my testimony.

## **The capability to make biological weapons**

The interest in biological weapons has been age old in the world, as has been the capability to use them. Biological weapons have been used at various times in recorded human history at levels of sophistication consistent with the time. In ancient times, biological weapons were crude. In modern times, they became sophisticated and highly lethal. In the 1960s, the capacity to make, disseminate, test, and evaluate biological weapons was transformed. At that time, the US government funded vast programs to develop biological weapons using science and technology that was cutting edge for those years. In those programs, they discovered how to make aerosols more stable in the environment; how to make particles float further; how to grow pathogens in high quantities; how to disseminate bacteria and viruses without inactivating them; and, much more. At the same time, other countries in the world were also studying biological weapons with their own dedicated, highly funded programs.

In 1969, President Nixon unilaterally ended the US offensive program. Then in 1972 he signed the Biological Weapons Convention saying that the US already had enough seeds of its own destruction. That treaty led to the end of the US offensive program and to the end of any country admitting it had a bioweapons development program, even though a number of countries were discovered to have had clandestine BW programs in the years since.

Now 40 some years after the signing of that treaty, the technology and know-how that was once the domain of governments, is now within reach of small groups of scientists around the world, even individual scientists with the right backgrounds. The methods for making aerosols stay airborne are widely available. The tools for making pathogens in high quantities in fermenters are on ebay. The recipes for making stable formulations of pathogens are on the internet. The equipment for disseminating these weapons is in hardware or agricultural supply stores. This information and technology is almost entirely dual use – in the sense that it has both legitimate and dangerous uses in the world. It can't be locked away, and it wouldn't be in our interest to do so.

I understand that this committee will soon have a classified hearing on the threat assessment. That will be important in giving you the US government assessment regarding what specific countries and groups are doing now with respect to research or development or stockpiling of biological weapons. All I will say related to this is that the workforce of scientists with microbiology and related relevant backgrounds that have enough knowledge to turn information and technology into bioweapons is countless and global. While particular threat briefings should help direct focus regarding specific terrorist groups' or countries' immediate interests in pursuing biological weapons, it is critical to understand that a country or group could change its direction on biological weapons in short order, quite possibly without any obvious signal. The former Soviet Union had a massive BW program for decades that was not visible to the outside. Given that small groups or even individuals are capable of making biological weapons and using them, we should expect not to have advanced warning regarding the development and their use.

In summary, the know-how and capability to create and use biological weapons exists widely in the world. This will only grow with time as the tools and techniques of biotechnology become more broadly disseminated, less expensive, and valuable to growing economies globally.

## **The consequences of biological weapons**

The anthrax events of 2001 were shocking for the country. Letters carrying anthrax spores were sent to a number of people in different cities. Hospitals, doctors and nurses at the time were largely unfamiliar with the disease. Elements of all three branches of government were each affected and closed at some point. Buildings had to be evacuated for prolonged periods. Cases appeared over weeks in different places. A number of people were sickened and killed. The source of the anthrax could not be identified. The communication about it from our own government was often uncertain and changing. The media coverage was constant. People were afraid of their own mail. Nothing like this had happened before in our country or any country.

A great deal has been done to improve our ability to recognize and respond to biological weapons events since that time. I will say more about that below. But it is important for this committee to know that a future biological weapons attack on the US could look quite different than the 2001 anthrax incident – in terms of size of attack, form, and the numbers affected.

The anthrax letters of 2001 came with a warning in them, which allowed some people to begin taking protective antibiotics and initiate evacuation. Future events are unlikely to come with warnings like that. It is more likely that the first sign of a bioterror attack will be sick people appearing in clinics and emergency rooms. And while the anthrax letters of 2001 came through the mail, future bioterrorism attacks could come in many different kinds of form. There are many means of creating aerosols. And there are clearly other means of using biological weapons against the public.

We also need to understand that the scope of future bioweapons events could be far, far greater than what we saw in 2001. In 2009, the US 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.” The use of such weapons could lead to substantial loss of life and great societal disruption. Even with a small or modest-sized attack, the social and economic impact would be significant.

## **Build our ability to respond**

In the last 10 years, progress in preparedness has been made in a number of areas. There are now a cadre of government officials, public health experts, doctors, nurses and scientists who have become knowledgeable and skilled in thinking through and planning for biological terrorism. That community of experts in and out of government didn't exist in 2001. There are also a series of major biopreparedness programs across the US government, some of which I will cite here. HHS/ASPR has funded hospital preparedness programs around the country and runs valuable programs like the National Disaster Medical System. NIH has a basic research program for

biodefense. BARDA has developed a number of medications and vaccines that could be critical in future bio responses. CDC has funded state and local public health agencies to prepare for bioterrorism (among other crises and disasters) and it oversees laboratory research in this area, manages a strategic national stockpile of medications for use in an emergency, and has an Emergency Operations Center that is a model for other health agencies around the world. DHS has created a risk assessment and threat characterization process to help guide planning. FDA has created an office that deals explicitly with the regulation and approval of products only to be used in the event of bioterrorism, pandemics or other urgencies or emergencies. The DOD and DOS have important programs dedicated to addressing the issue overseas through science and technology as well as cooperative threat reduction. Taken together, these efforts, combined with the substantial hard work of state and local public health agencies, hospitals, emergency management and civic organizations, have put the country on a better footing in its ability to respond to major biothreats.

Our Center's 2013 study of the US federal biodefense funding found that 90 percent of the biodefense budget served additional purposes beyond biodefense. The good news in that number is that these additional purposes are valuable such as public health agency preparedness for disasters, hospital planning for crises, and research that improves our response to infectious diseases. The down side of that 90 percent number is that there has been an inflated sense of what is actually been spent on biodefense; that effort is not nearly as big as it looks at first pass.

The more work that is done in this field, the more it becomes clear what we still need to prepare for to respond to bioterrorism and to sustain the preparations that have been made to date. What follows are my recommendations for what we need to pay particular attention to in the years ahead in terms of biopreparedness.

## **Strengthen medical and public health preparedness**

In the event of bioterrorism, the people who would be on the front lines responding are largely comprised of public health, medical and hospital professionals. They will be the ones most likely to discover that something has gone wrong and to initiate laboratory testing for what is behind it. They are the ones who will be called to rapidly investigate what is happening, and where and how the bioterrorism occurred. Following an act of bioterrorism, there may be no announcement, and there is likely to be no "site" that can be cordoned off - just sick people appearing in emergency rooms and clinics. Public health and medical leaders will be asked to advise our political leaders on the right course of action for administering prophylactic care to prevent illness, for treating those who are sick, for identifying those at greatest risk of falling ill. And they will be the ones who are providing medical care within hospitals.

Given the importance to bioterrorism preparedness of these professionals and the agencies and institutions in which they work, their work needs to be supported. Funding for the public health emergency preparedness program (PHEP), which funds state and local health agencies to prepare for bioterrorism and other disasters, has been cut by more than \$100M in the last 5 years. In addition, funding support for the national hospital preparedness program fell 33% last year, and is down nearly 50% from its inception. I'm really concerned about these reductions and trends,

and how this sharp decline in funding will weaken these programs. In fact, we are already seeing a dramatic reduction in total per capita funding for emergency preparedness in the states, which will inevitably result in a reduction in our capability to respond when emergencies strike.

It is worth calling your attention to the National Health Security Preparedness Index that was launched in December by 20 collaborating organizations. This is a first of its kind index that has as its purpose the measurement of the level of national and state health security preparedness. It uses 128 indicators that gauge state capacities and capabilities in the domains of health surveillance, incident and information management, countermeasure management, community planning and engagement, and surge management. Based on those indicators, scores are calculated that state and local preparedness communities and national policy makers can use to judge how well prepared we are, and how to continue to strengthen the collective efforts. The overall score for the country in December was 7.2 out of 10, with varying results in the states around the country. This score shows that we have built some capacity in a number of realms. But it also makes clear how much more we need to do. To make these scores improve will require focus and more resources. If, on the other hand, resources for these key national programs continue to slide, then I am concerned that index scores in the coming years will decline. We shouldn't let that happen.

Another critical element of our public health and medical preparedness is the development of medicines and vaccines for use following a biological attack. Development of these products is a complex, sometimes decade-long process with inherent risks of failure, as is the case with drug and vaccine development more broadly. It is difficult to persuade the major pharmaceutical companies to engage in this effort because of the uncertainties of government policy and action, and because of the opportunity costs associated with doing this work as opposed to other more economically valuable opportunities. A variety of programs and policies have been established over the years to try to deal with this challenge. Earlier critical steps to deal with this were the creation of the BioShield fund and the establishment of the BARDA advanced research and development program. The loss of the multi-year BioShield fund has been a setback for the USG effort to develop countermeasures. It creates new uncertainty for the private sector. The single year BioShield appropriation for FY14 is about equivalent to half of what had been available annually in years prior.

On the other hand, there has been a positive change in the way BARDA is now funded. In past years, advanced development at BARDA had been funded by diverting BioShield funds, which was not how the funds were intended. FY14 is the first year since FY2008 that BARDA advanced research and development has received funds from Congress directly and not from BioShield. It is important that BARDA continue to receive appropriations that are separate and distinct from BioShield. The purposes of BioShield and BARDA are distinct and should be funded accordingly.

Another major contributor to success in the program to develop countermeasures is the FDA program, established explicitly to support the regulatory process for these medicines and vaccines. This has been a highly successful program and should continue to get strong support.

It is worth underscoring again in the context of countermeasure development that we really need to come to grips with what was learned in the bioweapons programs from the 1960s. From those programs we learned that some biological weapons did not cause illness in the same patterns as naturally occurring infectious diseases. Among other things, they caused illness on an accelerated time course, and they had the ability to overwhelm traditional treatment strategies. As we continue to improve and build our countermeasure development efforts and broader planning efforts, we need to make sure our planning for today takes into account what we learned from those earlier years.

## **Make wise investments in biosurveillance**

The US government definition of biosurveillance comes from Homeland Security Presidential Directive 21. There it is defined as “the process of active data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health – whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin – in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity.”

We need biosurveillance systems to help us detect and understand new outbreaks and to discover specific signals related to bioterrorism or other health events. There are many information needs that would immediately and urgently arise following an act of bioterrorism: How many people are sick? By what means is the disease spreading? What are the risk factors and how do we control them? What public health interventions are working? Are treatments working safely and effectively? And many other related questions. We need systems that can answer these questions.

To do this requires good information systems, analytic capability and health expertise. At the federal level, that means sharing information across the agencies quickly. Information that can bear directly on outbreak discovery and control can come from public health, the agricultural sector, commerce, private industry, overseas disease surveillance networks, and many other channels. Programs like NBIC that are intended to share and organize that information across federal agencies and with state and local partners are critical. We should also support innovation and research into whether we can use social media and mobile technologies to identify outbreaks early.

At the local level, public health leaders also need information systems that give them insight into what is happening within hospitals during outbreaks. This requires collaboration between medical institutions and public health agencies in ways that helps them identify new patterns of disease in outbreaks, and gauges the effectiveness and safety of medicines and vaccines in automated, rapid fashion.

Disease surveillance also requires good laboratory diagnostics. When you ask public health officials what kind of surveillance information they place highest value on, they consistently tell you that laboratory data is the most prized because it provides definitive diagnosis of an illness or an outbreak. Laboratory diagnoses of serious infectious diseases that are made in a clinic or a hospital are not always automatically transmitted to public health officials who would be

responsible for communicating about them to the public and to political leaders. We also need to continue to push ahead to develop rapid diagnostic tests for bioterrorism related and other infectious diseases, recognizing that there is no commercial market for these products, so they will need continued government development support and government purchase.

A few words on environmental surveillance. I understand you will be holding a future hearing on this issue. So I will only comment here to say that there is a clear need for environmental surveillance, but it has to work in the real world situation where it will reside. If state and local public health agencies are to be part of the system (and they have expertise and tools that are needed for these systems to work), then they need to understand and believe in the value and the effectiveness of these systems. If state and local leaders don't have the confidence to take action following an environmental surveillance alarm when it goes off, then that is not a well-functioning system. So in addition to all the development, testing and evaluation of these environmental systems, a continued examination and testing of how they are actually working in places around the country is critical.

## **Improve global health security**

The work we need to do to prepare for bioterrorism has much in common with the work we need to do to respond to pandemic influenza, emerging infectious diseases, and antimicrobial resistance, particularly as we work with our international partners around the world on these challenges.

Each of these problems requires a workforce that knows how to recognize new outbreaks and new patterns of infectious disease. Each of them depends on scientific research to improve our understanding. Each of these issues could cause serious response challenges in the medical and public health communities. And in each of these realms, we have to cope with the reality that markets themselves have not been enough to create the new medicines, vaccines and diagnostics that are needed. The required preparations and responses to these issues are the same for our international partners as they are for us. It is important to see the ways in which working together on them makes sense and can create valuable synergy.

In conclusion, there has been consistent progress in recent years in our efforts to prepare for bioterrorism and related threats. But there remains a great deal of critical work to be done. Over the last decade, we have witnessed a slow but steady decline in attention to bioterrorism preparedness issues, in part because we haven't experienced another bioterror attack since 2001. But we have no reason – from a technical perspective or consequence management perspective – to let our guard down. I thank you for holding this hearing to address these issues. The efforts of this committee as well as other efforts in Congress can help to ensure we make continued forward progress in areas of great national importance in preparing for bioterrorism.