

**United States Senate**  
**Committee on Health, Education, Labor and Pensions**

*Facing 21<sup>st</sup> Century Public Health Threats:  
Our Nation's Preparedness and Response Capabilities*

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Chairman Alexander, Ranking Member Murray, and members of the Committee, thank you for the chance to speak with you today about *Facing 21<sup>st</sup> Century Public Health Threats: Our Nation's Preparedness and Response Capabilities*.

My name is Tom Inglesby. I'm the Director of the Center for Health Security of the Johns Hopkins Bloomberg School of Public Health and a Professor of Public Health and Medicine at the school. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University. Our Center's mission is to protect people's health from epidemics and disasters and build resilience in communities. We study the organizations, systems, and tools needed to prepare and respond, and work to help translate what we find into stronger programs and policies.

I will provide comments on the kinds of threats that the country faces, health care system preparedness, public health needs, medical countermeasure development, potential pandemic pathogen research and the global health security agenda.

**Public Health Threats to the Country**

The country faces a range of potential sudden, major public health threats, any of which could occur without much warning: natural disasters including major hurricanes, earthquakes, fires and mudslides; technological accidents; mass shootings and bombings; chemical spills and the use of chemical weapons, such as we saw on horrific scale in Syria; radiation and nuclear threats; and, biological threats, either natural, accidental or deliberate. I will say more about biological threats given the particular kinds of threats they pose.

We have seen signs of what natural epidemics can do in recent years. We saw what damage Ebola could do when it got into cities in West Africa, what MERS did in S Korea when it arrived there, how Zika could transmit congenital deformities by mosquito. And health agencies around the world are tracking H7N9 in China, the most serious of avian influenza potential threats to emerge in years, with case fatality rates on the order of 40%. If H7N9 ever evolved into a virus

capable of sustained human to human transmission, it is hard to describe how devastating that would be to the world.

We are also now in an era where there is incredible power in biotechnology and science. This power is almost entirely for the good, with the development of new medicines, better agriculture, improvements to the economy, and more. But with every new technology we need to acknowledge the potential downsides of accidental or deliberate misuse. It is now possible to engineer new traits into old viruses. For example, it is becoming possible to take the lethality of one virus and combine it with the contagious qualities of another virus. And, last week scientists published research showing how they synthetically could create horsepox, a close viral relative of smallpox. We don't have the oversight system we need to fully understand or manage these kinds of developments yet, either in the US or internationally. Whatever we do about this, we need to ensure that we don't slow down science that drives so many good things forward. But we also can't ignore that new risks are becoming possible.

Even without the advent of new science, there are the known deliberate biological threats including anthrax and smallpox. The government's own modelling has shown repeatedly how severe the impact could be in the event of larger scale biological weapons use in the US, and there is continued urgency in preparing for these possibilities.

There is a broad range of potential consequences from biological threats. Some are common and of a more modest scale. On the other end of the spectrum, some conceivable scenarios could even pose globally catastrophic biological risks, with lasting damage to countries and societies around the world.

Given the range of biological scenarios and possible consequences, the forthcoming White House National Biodefense Strategy will be of great importance in helping to set national priorities, assign agency responsibilities, and identify funding requirements.

### **Health Care System Preparedness**

An essential component of medical preparedness is the capacity to care for high numbers of sick or injured in the event of an emergency. And while there has been substantial progress in preparing for smaller disasters, the nation is not ready to provide medical care in large catastrophes or big epidemics of contagious disease.

For smaller events, there is evidence that preparedness has gotten better. We saw this with the response to the Boston marathon bombing in which 264 were injured and treated at 27 hospitals – all victims who made it to the hospital survived. The health care and EMS response to the Las Vegas shootings was also considered to be effective in providing trauma care. Hospitals, for the most part, do well in normal flu season, handle smaller outbreaks, and they provide good care for the victims of car and bus accidents. The Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) has been working to help fund and build these capabilities.

In larger scale infectious diseases emergencies, most US health care systems would not do well. It was quite evident how difficult it was to care for even one hospitalized Ebola patient, let alone to consider how a hospital would handle a larger scale infectious disease emergency. The ASPR program to build 10 regional biocontainment units (BCUs) was smart, and we should build on that capacity. But it is important to know that most of these units can handle only a couple of patients at a time. More broadly, there is no surge plan for taking care of larger numbers of patients with contagious, potentially lethal infectious diseases. If hospitals do need to take care of patients with contagious infectious diseases, there could be major disruptions to the regular operations of their systems. They will need to protect against that, or could put at risk their normal work of taking care of heart attacks, delivering babies, performing surgeries, and more.

If you consider what would be required to manage the ill in a flu pandemic or smallpox or after a sizable anthrax event, it is clear that hospitals do not have that capability – they are simply not equipped for those larger events, and they are living too close to the margins with just in time inventories to be able to surge.

In larger events, a responding hospital would need to be part of a larger entity that connects hospitals to each other and to other key parts of the system – a system called Health Care Coalition. HPP has funded the creation of these coalitions around the country, and they largely comprise of hospitals, public health, EMS. In places where they don't already, coalitions should also include minute clinics, surgi-clinics, pharmacies, mental health and dialysis centers. We saw in the response to Hurricane Sandy just how much medical care is delivered in the community outside of hospitals themselves, so these kinds of organizations need to be prepared to respond in emergencies too. With the hurricanes of last fall, we also saw how much the affected communities relied on the assistance of ASPR, the emergency personnel it led, and the emergency medical assets it helped to provide.

On a national level, for planning for major epidemics and disasters, we should build on the strengths we see in Level 1 Trauma Centers and the BCUs to create what could be called specialized Disaster Resource Hospitals (DRH). These would be designated facilities with special national and regional responsibilities to prepare for disasters and epidemics. They would have more reserve in the system, better trained people, resources to support a larger mission, and could serve as resources to other hospitals. Many would be academic medical centers, probably already Level 1 Trauma Centers, probably many would be the existing BCUs, because they are already organized to take on high end risks and problems that smaller hospitals in system can't manage.

There are other actions we can take to improve our health care response. Doctors and nurses should be able to take their healthcare credentials across state lines in order to facilitate response to a regional or national emergency.

We should also be able to rapidly deploy clinicians internationally in new outbreaks. We had substantial difficulty doing that in Ebola. It would be good for ASPR to work with CDC, State Department, USAID, DoD and other partners as needed to develop a plan delineating under what conditions, with what personnel, and how clinicians would be officially deployed internationally from the US in the event of a pandemic or other emergency of international concern. Early deployment of clinical experts could help outbreaks overseas from becoming out of control and spreading.

And, the US government should put in place a plan for conducting research during public health emergencies to study new medicines, vaccines, and other clinical and public health interventions to gauge whether they are effective and safe. We have seen in past epidemic responses that a number of new products and efforts are tried, but not necessarily in careful ways that create the evidence needed to determine effectiveness and safety. Clinical trial designs that help us answer those questions should be worked out ahead of any crisis.

Overall, we need a stronger approach to prepare for the most serious catastrophes that could hurt the country. We need planning for the most consequential of the FEMA national planning scenarios. In the dozen years since these scenarios were issued, we have not made a lot of progress in the health care system in being able to respond effectively to many of the threats detailed in those scenarios. A vivid example of this was Hurricane Maria that destroyed the basic infrastructure that we need to provide medical care to victims.

In terms of resources, the HPP budget of \$250M is down from \$515M at its inception. This is worrisome, given what we have learned about how hard it is to prepare to provide mass care for the range of emergencies experienced by Americans. The HPP program should be supported at a higher level, and other avenues of funding should be explored for funding a new DRH program. Possible additional federal funding avenues to explore include adding a modest amount of additional reimbursement for each Medicare and Medicaid admission to DRHs. This could help reduce the uncertainties surrounding annual appropriations for preparedness that come through the annual HPP program. In any event, ASPR and its mission to build national preparedness, including the hospital preparedness program and the medical countermeasure enterprise, need to be strongly supported.

### **Public health preparedness**

Another national pillar for preparedness is the capacity of our public health system to detect and respond to public health crises. Since 2001, there has been a major effort at CDC and around the country at a state and local level to build programs that would help provide early warning of new outbreaks, provide laboratory diagnostics, investigate and help contain outbreaks, communicate risk to the public, ensure biosafety and biosecurity practices and more.

A great deal of progress has been made, and there is a committed cadre of public health officials working on these issues around the country to protect Americans during times of public health crisis. But there is too much to do and not enough trained professionals to do it. The public health workforce has been reduced by budget pressures by tens of thousands in the last decade. This is the same public health workforce that every day deals with urgencies like the opioid crisis, a nasty seasonal flu season, outbreaks of diseases like measles or norovirus in a school or meningitis on a college campus or legionella in an apartment building, medicine and vaccine shortages, HIV, hepatitis, tuberculosis, the safety of water supplies, and so much more. The National Health Security Preparedness Index, which measures state by state capacities in key areas of public health, shows an average state score of 6.8/10, with substantial variation around the country.

Public health agencies critically rely on funding from the Public Health Emergency Preparedness Program (PHEP) program administered by the CDC to prepare for emergencies. That funding

has been reduced to \$660M from \$940M in 2002, and yet the public health crises faced by Americans have not commensurately declined. Early in 2018, the Administration proposed substantial cuts to PHEP grants. Congress didn't go along with those cuts. I am hopeful that this year, the Administration will recognize the role of the PHEP program and public health grants in preparing the country for disasters and epidemics that befall our communities. There should be more funding for public health preparedness for emergencies, not less. If current funding goes down or away, public health jobs are cut, key labs don't get supported, outbreak investigations will be slowed, disease surveillance programs will suffer, along with the rest of what public health provides every day and in emergencies.

Some have asked whether there should be changes made regarding which states and cities should receive HPP and PHEP funding based on some new determination of risks. We haven't seen evidence that serious changes to the programs' formulas would provide meaningful benefit or that the current formula is flawed (currently there are already risk-based considerations in both formulas). Funding formulas that lean too heavily on risks from prior natural disasters ignore both universal risks, such as an influenza pandemic or other outbreaks, and unpredictable threats such as acts of terrorism and mass shootings. Because disasters can occur anywhere in the U.S., preparedness should occur broadly around the country.

Within CDC too there are essential public health preparedness programs that should be noted, including the programs that provide support and technical preparedness assistance to states and local public health agencies; the Biosafety and Select Agent and Toxin program; the Strategic National Stockpile of meds and vaccines we will need in crises; a range of critical disease surveillance programs; and, the Emergency Operations Division which is the nerve center for CDC's deployments around the US and the world. These programs need to continue to be supported.

There is a new proposed element in public health preparedness that should be supported – a Public Health Emergency Contingency Fund. We saw during the initial response to Zika that it took more than 230 days to get emergency appropriations for that epidemic. A way to address this would be to create a new Fund that allows rapid access funds in the aftermath of an emergency. Such a fund should supplement and not supplant existing public health and preparedness grants which are needed in order to have a public health essential work force, labs, and infrastructure in the first place, and to prepare for the range of disasters and epidemics that could arise. A Public Health Emergency Contingency Fund would allow rapid initiation of responses to acute emergencies so that families and children wouldn't have to wait for a special appropriation before help could start. Resources from that fund could be made available immediately following a public health emergency declaration, with reporting requirements to Congress following the initial emergency period and an automatic process to replenish funds when depleted. A balance of \$500 million to \$1 billion would be appropriate based on past emergency appropriations for Zika, Ebola, and H1N1. It would be enough to get the emergency response started for public health, the healthcare system, and for initiation of medical countermeasure development, but may not be sufficient for the extended response, which would need to come through emergency Congressional appropriations.

### **Medical Countermeasure Development**

Another essential component of the country's medical and public health preparedness is the capacity to make medical countermeasures to respond to threats. As of 15 years ago, there was

no national approach to medicine or vaccine acquisition for civilian needs in emergencies. Since then, there has been substantial progress. There are now: a research program at NIH; an advanced development program at BARDA; an FDA program dedicated to medical countermeasure approval and regulatory science; engagement of the biopharma companies which develop and manufacture needed products; and, a substantial stockpile of medicines in the National Pharmaceutical Stockpile.

But we need to keep strengthening and sustaining this medical countermeasure research, development and stockpiling system. It is a very challenging mission primarily because of the complexity of the science and the breadth of the needs. It is also difficult because - outside of the US government and sometimes other governments or international organizations - there are no commercial markets for most of these products. So the country relies on this system to prepare for a range of biological, chemical and radiological threats.

There are a number of things about medical countermeasure development that are worth special mention. We have to press forward on new approaches to flu vaccine. We certainly need to forge ahead as rapidly as is possible in the development of a universal flu vaccine which could provide broad coverage to the range of flu threats that could face the country. But our best flu scientists say that there are major technical challenges in that pursuit, and that it will take time to develop a universal flu vaccine, no matter how we approach it. So in the meantime, we need to do all we can to improve the flu vaccine approaches that are now available.

For instance, we still rely on eggs to produce annual flu vaccine as we have for years. We do this even though we have the technology to produce vaccine using modern recombinant techniques. Using new production approaches would allow us to accelerate our response in the event of a flu pandemic. It would also lessen the chances the vaccine strains could drift to become less effective in the manufacturing process as can happen in the process that relies on eggs.

In the event of the onset of a pandemic flu, the USG working with its biopharma company partners have a plan that will take 5 to 6 months to begin delivering the needed flu vaccine for that pandemic. We should continue to exercise and support that plan and work to accelerate that timeline. But at least in the case of flu, we do have targets and an exercised process to go from new pandemic discovery to vaccine manufacturing in 6 month timeline. We don't have that kind of process for epidemics that might be caused by other pathogens.

For example, during the Ebola outbreak in West Africa, a new Ebola candidate vaccine was developed, but it took so long that it was not available until after the outbreak was over. And in some ways, we were better positioned to respond to Ebola than we would be for many other diseases -- there had been substantial science efforts related to early Ebola countermeasure development in DOD and NIH programs for years. For other infectious diseases, we would be further behind at the start, and it could take much longer than it did for Ebola.

As per the November 2016 PCAST report to the President on *How to Protect Against Biological Attack* recommended, the country should set a national target of 6 months or less for developing a new medicine or vaccine for major epidemics and pandemics beyond pandemic influenza. To do that would require people, systems and infrastructure dedicated to that goal within

government, and a budget to go with that. Right now when new epidemics emerge that require a sudden start of a new MCM program (e.g. Zika), it is almost guaranteed to be a long, uncertain, and complicated process with no clear or well worked-out pathways. In the case of Zika, a major company that was developing the vaccine ultimately dropped out of the process, in part because of the challenges of working with the government.

### **Potential Pandemic Pathogen research**

It is also important for the medical and public health preparedness community to pay attention to the kinds of new threats that could inadvertently come from biological research. For example, it was announced last month that the USG moratorium for funding potential pandemic pathogen (PPP) research is over. It is possible once again to apply for USG funding to study ways of making the world's most lethal viruses (like H5N1), respiratory transmissible (like seasonal flu). In the worst case, this could lead to the accidental or deliberate release of a novel strain of virus that could cause an epidemic, or even a pandemic. I don't believe the benefits of this kind of research are worth the risks of doing it. But since the end of the moratorium has occurred, I would make a number of recommendations regarding this program.

There should be transparency in how the government approaches this research. Agencies that fund this work should make their processes public. What PPP experiments are being proposed? How were risks and benefits determined, what experiments were approved, and which were denied? What kind of biosafety and biosecurity will be required to do this work? There should be clarity regarding the special review process that has been established to handle this research. How will it work? Who will be involved? How to avoid conflicts? Are there red-lines that should not be crossed by scientists?

What will the international approach be? It is good that US has taken a lead in formulating new PPP framework given that the USG provided the majority of government funding to date for this kind of work. Since the USG has acknowledged there are high risks in PPP, what will USG do internationally to help establish norms for this? What will our reaction be if we learn that other countries are pursuing PPP research? I disagree that the US should be pursuing this work, but if the US is going to do it, then it should be working to engage other countries to try to establish rules of the road regarding under what conditions it will be done.

### **Global Health Security Agenda**

A final element to note in medical and public health preparedness is the importance of international programs in preventing the emergence of major outbreaks that have the chance to spread to the US. In 2014, the US helped to launch the Global Health Security Agenda (GHSA) to improve the capacity of countries around the world to prevent, detect and respond to infectious disease threats. One lesson from Ebola was that we have to do more to help countries control infectious diseases. Because of that experience and because so many other countries were having trouble building basic capacity to detect and respond to infectious diseases, the US made a \$1Billion commitment to the GHSA for a period of 5 years. Other countries have also been big supporters of this effort. South Korea has pledged to spend \$100 million to build capacities in 13 countries. Japan and Australia have pledged \$40 million and \$100 million, respectively.

With US GHSA funds, the CDC and USAID have been working to improve these capabilities in 39 countries around the world. These programs work to diminish antimicrobial resistance, increase laboratory and surveillance capacities, improve vaccination rates, strengthen the public health workforce, and much more.

But at this point the future of the GHSA is uncertain. Even though a number of senior officials in the Administration have voiced support for the GHSA, and signed onto a declaration to extend the GHSA for another 5 years, US funding for the initiative is ending soon, and no commitment for future financial support has been made. Without any sign that funding will be continued, CDC has notified countries that it will begin planning to shut down those programs. And if we pull away from the GHSA in this way, other countries that provide funding and technical assistance will also likely do the same.

US leadership in the GHSA not only has the advantage of improving the capabilities of countries to prevent, detect and respond to infectious diseases. It is also, as US Secretary of State Tillerson said last year, vital to US national security interests. If vulnerable countries (many of which are either politically or financially unstable) do not have the capacity to quickly cope with disease outbreaks, those outbreaks are more likely to spread internationally, including to the US. The GHSA is a powerful tool for helping to ensure that global gaps in health security are addressed before disease outbreaks occur. To continue the pace of US efforts for the GHSA set by the original US investment and programs, an estimated \$100M to \$200M annually would be needed. It is important for the United States to commit to support the GHSA to help protect the nation and the rest of the world from epidemic disease. Over time, as countries build their own capabilities, the need for the US and other national commitments should diminish. But at this time, GHSA remains a central element in building international capability to prevent, detect and respond to epidemic diseases.