

**Committee on Homeland Security
U.S. House of Representatives
Invited Testimony**

Brett P. Giroir, M.D.
Chief Executive Officer, Texas A&M Health Science Center
Director, Texas Task Force on Infectious Disease Preparedness and Response

Dallas, Texas
October 10, 2014

Chairman McCaul and members of the committee:

I am Dr. Brett Giroir, Chief Executive Officer of Texas A&M Health Science Center, and Professor in the Colleges of Medicine and Engineering. By training, I am a critical care physician-scientist with specific experience in treating life threatening infectious diseases. I also have experience in the federal government as Director of the Defense Sciences Office at the Defense Advanced Research Projects Agency (DARPA) and Chair of the Chemical and Biological Defense Panel of the Department of Defense Threat Reduction Advisory Committee. In addition, earlier this week, Governor Perry named me Director of the Texas Task Force on Infectious Disease Preparedness and Response.

The risk of infectious disease outbreaks is real, and these outbreaks are inevitable given the interconnected nature of the world we live in. An outbreak anywhere becomes a threat everywhere. Given our location along the U.S. border, our experience with major natural disasters, and our unique assets such as the Galveston National Laboratory and the Texas A&M Center for Innovation in Advanced Development and Manufacturing (CIADM), Texas is on the front lines of public health preparedness and protection.

In response to the first case of Ebola diagnosed in the U.S., Governor Perry swiftly established the Task Force on Infectious Disease Preparedness and Response to assess and manage the risk in Texas and to prospectively plan for future infectious disease threats – whether natural or the result of bioterrorist attacks. The Task Force includes internationally recognized infectious disease and public health experts, seasoned biodefense leaders, and state agency professionals across major areas including health and human services, emergency management, public safety, transportation, environmental quality, public education, and housing and community affairs. The members of this task force volunteered in order to serve the people of Texas, and as a result, the nation, and each of us has accepted this call to duty from the Governor for that sole purpose.

There is no question that there will be opportunities for increased performance across many of the complex elements that have been brought together to effectively contain Ebola within Texas. Remember, this was the first Ebola patient to be diagnosed in the United States. If there is room for improvement, we will work to assure that Texas learns, documents, disseminates information, and implements optimal changes to further protect our citizens – and that the United States, as a whole, benefits from the process. The Texas Task Force took action right away, meeting for the

first time immediately after the Governor issued the Executive Order, and we have been actively engaged in assessments and discussion since that time. We have preliminarily identified six areas of focus that have been prominent in the current Ebola response, and we believe that these areas will have implications for many potential disease outbreaks should they arrive in the United States. These areas include:

1. Hospital Preparedness and the Potential Role of Improved Rapid Diagnostics
The Task Force will focus on the initial identification of a patient, or potential patient, and the education and preparedness of diverse health care professionals essential for this key step in the containment process.
2. Command and Control Issues
The Task Force will focus on processes related to the initial activation of the Incident Command Structure, integration of local, state, and federal resources, development of a common operating picture, and the unique differences of a public health challenge, such as an Ebola patient, compared to the challenges experienced in natural disasters such as hurricanes.
3. Organization and Implementation of Epidemiologic Investigations and Monitoring
The Task Force will assess opportunities for improved integration of disease tracking, data and information synthesis, and potential opportunities for automated technologies and scalable common data platforms that could be shared at the local, state, and federal levels.
4. Decontamination and Waste Disposal
The Task Force will review and assess a plethora of issues faced in this area, including but not limited to: determining what could be decontaminated, versus contained-hauled-incinerated, availability of appropriate containers, logistics of transport, and complex permitting issues across multiple levels of jurisdiction.
5. Patient Care Issues
The Task Force will examine how to improve information flow to front line care providers, including information on new drugs, their risks and potential benefits, and how they might be accessed under investigational protocols.
6. Care of Patients Being Monitored.
The Task Force will examine the diverse needs of individuals under monitoring or controlled monitoring, including the needs for basic necessities, such as food, clothing, and housing, as well as potential needs for social services and/or counseling. Due to the rich diversity of the Texas population, cultural competency in communication and interactions are important aspects of this area.

The Task Force will submit initial draft assessments and recommendations by December 1 for consideration by the Office of the Governor and Texas Legislature, so that actions requiring statutory changes could be proposed in the 2015 legislative session. In the meantime, the Task Force is committed to insuring that the teams on the ground have all necessary expertise and resources at their disposal to respond to the potential for additional Ebola cases in Texas, and to begin the process of developing an infectious disease preparedness and response plan to

complement the State Emergency Management Plan already in place and proven highly effective in response to natural disasters.

Regarding the current situation here in Dallas, the response and coordination of local, state and federal resources has generally been very good, but the Task Force will seek opportunities for improvement at all levels of collaboration and integration. Looking forward, the issues at hand are highly dependent on the larger security and preparedness system. State and local planning is critical, but so is clear and defined support to local and state authorities from the federal government, including the Centers for Disease Control (CDC) and Office of the Assistant Secretary for Preparedness and Response (ASPR). While there have been lessons learned, the successes in controlling this potentially dangerous situation are a testament to the incredible skill and dedication of all those on the ground in Dallas, who in my mind are nothing less than national heroes.

Gaps in Hospital Preparedness and Public Health Infrastructure

It is important to understand that our state's and the nation's public health infrastructure has been subject to significant funding reductions in the Federal Hospital Preparedness Program (HPP), which is intended to provide funding and support to improve surge capacity and enhance community and hospital preparedness for public health emergencies. These funds are expressly for enhanced planning at the state and local level, for increased integration across the public and private healthcare sectors, including hospitals, and other healthcare organizations and providers, and for improving infrastructure for public health emergencies. It should come as no surprise that hospitals require public funding to train and prepare for what are low probability yet high consequence, and potentially catastrophic, events.

HPP is meant to provide the foundation and core for exercises and ability to respond and get information out so that the nurse or physician on the front line would contemplate Ebola or anthrax in their differential diagnosis. HPP has been cut significantly in recent years by the federal government, and these actions have had clear, identifiable consequences here in Dallas. In fact, during the Federal Budget compromise last year, HPP funds were diverted to fund the Biomedical Advanced Research and Development Authority (BARDA) rather than use another funding source that was suggested by Congressional leaders. While we are very thankful this action allowed BARDA to continue operations (especially since the importance of its mission has been made abundantly clear during this Ebola response) robbing Peter to pay Paul has left us less far less prepared than we could have been, and indeed should have been. This must change if we are to be prepared for public health emergencies, now and in the future.

Guidelines for Health Preparedness and Technological Field Support

In January 2012, ASPR issued "Healthcare Preparedness Capabilities," providing national guidelines for healthcare system preparedness. Unfortunately, several of the critical capabilities identified in the report remain problematic areas in our public health preparedness and response infrastructure.

For instance, ASPR recommendations address the ability to coordinate multiple agencies and their decision-making, to provide incident information sharing, to manage resource

implementation, to provide an inventory management system, and to notify stakeholders of healthcare delivery status. In reality, the incident command team does not have the necessary technology in place to provide data tracking and analysis that would support the prescribed common operating picture across the multiple layers necessary to coordinate an effective and integrated response. Currently, information is housed on individual laptops and other devices, being reported manually, and compiled once or twice daily for the Texas Department of State Health Services Commissioner, Dr. David Lakey, who is leading the response in Dallas, and to whom we all owe a debt of gratitude, along with his colleagues in the CDC and other responders, who are working around these technological coordination challenges to the degree possible.

Another critical capability outlined by the ASPR report, Information Sharing, is to “Provide healthcare situational awareness that contributes to the incident common operating picture.” This critical capability has not been realized in the current Ebola scenario. In short, our public health infrastructure has not kept pace with technological and communications breakthroughs that are now widespread, and also has not yet incorporated tools to facilitate data collection, analysis, communication, and decision-making. This reality must be acknowledged by ASPR leadership, and a strategy to address these significant challenges should be developed in partnership with the caregivers at the epicenter of the current Ebola containment mission.

National Inventory of Potentially Available Ebola Therapeutics

Another major gap is the lack of any sort of inventory of candidate therapeutics to treat Ebola patients who are brought to the U.S. for treatment or who are diagnosed in our country. The fact of the matter is that we had a person fighting for his life on American soil and no easily available information about drugs available to administer. This is not a new issue; Dr. Keith Brantley received ZMapp in August by hearing about it from a colleague, not from U.S. federal authorities. Unfortunately, because of a number of issues as further described in this testimony, ZMapp was not available to be given to Mr. Duncan.

The federal government should provide a timely and frequently updated list of all possible medical countermeasures to treating physicians or to appropriate state public health officials. This list should include a concise summary of risks and potential benefits, instructions for how to obtain these therapies, and also should insure that there are specific research protocols in place to capture the meaningful data that will be generated through the use of these drugs. Today, physicians and patients often must track down the companies directly and ask for the drug candidates, or officials such as myself use personal contacts within the government to provide as much information as possible to the hospital treatment team. This is both inefficient and time consuming – and thus leaves patients and doctors less than optimally equipped in this struggle for life and death of a critically ill patient. This is completely unacceptable given the more than decade-long effort the federal government has undertaken to evaluate and advance medical countermeasures.

In terms of availability of therapies or vaccines against Ebola, our country is woefully and indeed frighteningly deficient. While it is true that the mainstay of Ebola treatment is supportive care, that is only the case because we have little else to offer. It is my personal assessment after experiences in both the academic and federal sectors that this deficiency relates less to scientific and technical obstacles, than it does to the lack of federal prioritization of the efforts; lack of

clear federal leadership accountability; and difficult, if not oppressive, contracting procedures that are often at odds with the iterated national strategy and objectives.

Special Assistant to the President on Biodefense

When Congress created the Assistant Secretary for Preparedness and Response role in 2006 as part of the Pandemics and All Hazards Preparedness Act, ASPR was intended precisely for the kind of situation we face today with Ebola. The nation was to be provided with a Senate-confirmed assistant secretary to take an all-hazards approach to bring to bear all necessary resources, regardless of where they belong on the federal government's organizational chart. That resource exists today in ASPR, but what is critically lacking is a White House Special Assistant to prepare for and lead such responses. Unfortunately, that position was eliminated by the current administration in January 2009.

We commend Chairman W. "Mac" Thornberry and James Langevin, Ranking Member, of the House Armed Services Committee subcommittee on Intelligence, Emerging Threats and Capabilities, for their April 22, 2014 letter to the President on this very topic, in which they call for the appointment of a Special Assistant to the President for Biodefense. This position has existed under both the Clinton and Bush administrations but was eliminated early in 2009. The letter notes that "there are at least 12 separate government agencies with biodefense responsibilities." As pointed out in a 2001 U.S. Government Accountability Office report, "Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue," there are more than "two dozen presidentially appointed individuals with some responsibility for biodefense."

Contracting Authority

ASPR, which is housed within the U.S. Department of Health and Human Services, oversees BARDA and the Office of Acquisitions Management, Contracts and Grants (AMCG). Several years ago an administrative decision was made to centralize all contracting under AMCG, and remove it from under BARDA's responsibility. While this made sense at the time, in practice, this has significantly slowed BARDA's efforts to move medical countermeasures through the manufacturing pipeline. Returning contracting authority to BARDA would certainly clear the way for the development of medical countermeasures, including experimental Ebola therapies. I want to specifically state that my team, and indeed most if not all of the scientific and technical community, has great respect for the leadership and technical expertise of BARDA. Without BARDA, the country would be gravely behind the curve without even the basic national response infrastructure to address this problem, or ever-present global challenges such as pandemic influenza.

Texas A&M CIADM AND Ebola Therapeutics

As you know, the Texas A&M Center for Innovation in Advanced Development and Manufacturing is a public-public-private partnership with the U.S. Department of Health and Human Services and one of three government-funded biosecurity centers designed to enhance the nation's preparedness against pandemic influenza, and chemical, biological, radiological, and nuclear threats by accelerating the research and development of vaccines and therapeutics, and

rapidly manufacturing these products at scale in cases of national emergencies. The Texas A&M CIADM is responsible for producing 50 million vaccine doses within four months of a declared influenza pandemic and receipt of the viral strain. It is also responsible for having the capabilities to manufacture, at scale, vaccines or biological therapeutics required for an outbreak, such as Ebola, if requested by the federal government. Our team is made up of leading academic, non-profit, and commercial partners including GSK.

The Texas A&M CIADM represents a long-term, strategic initiative – sponsored by BARDA – to assure preparedness by creating indispensable infrastructure and staff capabilities to rapidly respond against highly diverse threats. The CIADM will deliver on several critical objectives, including:

- Ensure the U.S. can develop and manufacture life-saving vaccines and therapies quickly, flexibly, and cost effectively at scale;
- Improve the ability to protect the health of Americans in response to emergency situations; and
- Train an expert workforce that can fill the needs of national biosecurity for the next generation.

The Center stands ready, and if called upon, will compete for manufacturing of a wide range of vaccines or therapeutics required by the U.S. government, including products against Ebola. Texas A&M Health Science Center also has a proprietary vaccine candidate now in preclinical evaluation that holds promise as one of the weapons against this growing global threat.

In closing, I thank you Chairman McCaul, and the members of the Committee for your leadership and for engaging on this important series of challenges that I have outlined. The members of the Texas Task Force and Texas A&M Center for Innovation want to be seen as your partners in solving the current Ebola situation in Texas and building a resilient and prepared homeland that can overcome threats, regardless of the source. I am honored and privileged to serve as resource to you now and going forward.