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STATEMENT

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"BIOTERRORISM AND PANDEMIC INFLUENZA: ARE WE PREPARED?"

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Chairman Gregg, Senator Byrd, and distinguished members of the Homeland Security Subcommittee of the Senate Committee on Appropriations, it is a privilege to appear before you today to testify on this subject of national importance. Your leadership on preparedness issues related to bioterrorism and pandemic influenza in particular is both crucial and commendable. While our federal, state and local governments as well as the private sector and healthcare community, have taken steps in the right direction, our level of preparedness remains a work in progress and it is not yet where it needs to be. Five years ago, the Senate Committee on Foreign Relations invited me to testify on the threat of bioterrorism and how we, as a nation, might best organize and marshal our resources so as to meet that threat and combat the spread of infectious diseases. At the time, I suggested that the country was "at a crossroads" and that, "[w]hile credit must be given where it is due, the time has come for cold-eyed assessment and evaluation…".[1] These words are equally apt today.

Neither bioterrorism nor pandemic influenza is a challenge for the federal government alone. It is at the state and local level that the rubber will truly meet the road, and it would be folly to try to micromanage these matters from Washington. What federal leaders can and should offer, however, is clear guidance to their partners at the tip of the spear, including hospitals and healthcare providers, so that expectations are framed in realistic terms in advance of an event and preparedness plans are implemented effectively. To this end, several pieces of federal legislation already exist on the bio-defense side, and with respect to pandemic flu, the President issued a National Strategy in November 2005, followed by an Implementation Plan earlier this month. Collectively, these initiatives and many others undertaken help move the ball forward by defining parameters for action and serving as a spur to it. The danger is if we allow these measures to instill a false sense of security, when we should be asking ourselves honestly whether we are truly prepared.

The good news is that important strides have been made. For instance, it is no exaggeration to say that we are a global leader in terms of pandemic preparedness (while recognizing that this is not an area where we can go it alone; to the contrary, international partnerships are, and will remain, crucial). Certainly Secretary Leavitt's national tour, reaching out to all US states to foster tailored, jurisdiction-specific response efforts, is laudable. At the end of the day, though, it all comes down to implementation and execution. Yet currently we are experiencing a "plandemic" – a proliferation of plans. Unless and until the focus shifts to competent execution, the nation's preparedness posture will not be solidly grounded.

Similarly, extant legislation concerning bio-defense is in principle an important piece of the puzzle but, in practice, there have been difficulties with applying the law. While challenges including the financing of vaccines and countermeasures have been partly addressed by legislation such as the Project BioShield Act of 2004, delays have plagued the process and framework established by that law. By way of illustration, only a handful of the roughly sixty "material threat" assessments envisioned by BioShield have actually been completed. Further, while BioShield addressed the need for a guaranteed market for countermeasures, the so-called "valley of death" problem relating to investment in advanced development remains, and there is still a lack of clarity regarding who is in charge of the overall effort. This sends the wrong signal to industry and the manufacturing community, which are crucial components of the solution, and is at odds with the public interest.

These areas which could stand improvement highlight a broader issue, namely the convergence of public health and national security. This intersection gives rise to a pressing need for careful coordination of a range of matters including budgets and resources, policies and programs, and organizations and structures. Despite this need, the various moving parts of the preparedness and response enterprise are not yet as synchronized and harmonized as they ought to be. Indeed, ongoing debates such as that over where to situate the National Disaster Medical System (NDMS) suggest that we are still stuck in neutral, and not using our time and mindshare to best advantage. Focusing on where to place the NDMS is a distraction from the real issues, which are function and capacity – where NDMS sits is at best a subsidiary matter, so long as it gets the job done. To do so, the NDMS must be empowered with the authorities and resources required to effectively execute the mission, whether within the Department of Health and Human Services (HHS) or the Department of Homeland Security (DHS).

From Plans to Planning

To shrink the delta and get to where we need to be in terms of preparedness, the most critical first step is to shift our locus from plans to planning and execution. Doing so will require the development and elaboration of doctrine – something that has never been done in a meaningful way for bio-defense. Without significant doctrine, however, all of our best-laid plans will remain paper tigers, never translated into action or operationalized. As we transition squarely into the realm of implementation, moreover, it will be crucial to thoroughly align the National Response Plan (NRP)

with, among other things, the National Pandemic Influenza Strategy and Implementation Plan. The potential for conflict clearly exists given the NRP's focus on events that are both geographically and temporally concentrated – characteristics not shared by the pandemic phenomenon. Being prepared means standing ready to exercise command and control through a fully integrated incident command system. Unless the NRP and the President's Implementation Plan fully mesh with each other in actual operational terms, we will have nothing more than a series of plans to plan.

Leveraging an All-Hazards Approach

Underlying the NRP is an all-hazards approach, which should consistently guide our planning and preparedness efforts. Too often, and to our detriment, we have allowed ourselves to become focused on the "crisis du jour." While recognizing that there are important differences when it comes to preparedness for bad weather, "bad guys," and "bad bugs," we should aim to leverage the fact that many similarities exist. Measures undertaken to prepare for a pandemic, for instance, will not constitute wholly sunk costs even if a pandemic does not materialize. Many of these steps will have broader applicability and we should bear that in mind while also seeking to maximize secondary and tertiary returns on our investments, beyond simply guns, guards, and gates.

Public Health Capacity – The Touchstone

Our medical and public health response structures are the foundation upon which all else rests. To meet the challenges posed by bioterrorism and pandemic influenza, these structures must be shored up and bolstered. A uniform system, whose hallmark is enhanced public health capacity, must be built nationwide. Every community must have surge capacity. Admittedly, this is an ambitious goal, especially when market forces press in the opposite direction, against the creation or maintenance of any excess capacity. It is also important to consider that the safety net that is the NDMS may be of limited value if there is a need to maintain those healthcare practitioners in their local communities. The challenge is not insurmountable though, and Homeland Security Presidential Directive 8, which establishes the National Preparedness Goal (NPG) and accompanying scenarios, demands nothing less. Expanding the medical reserve corps would certainly be one step in the right direction.

Concerning bioterrorism in particular, two areas merit heightened attention and focus. First, with respect to the Strategic National Stockpile (SNS), it is crucial that

there be a robust capability not only to deliver needed items to affected communities, but also to rapidly distribute prophylaxes once they have arrived on-site. Depending on the situation, it may be possible to convey the relevant items directly to affected residents. When a healthcare provider is not required in order to administer the treatment, it may be possible to draw on existing distribution and delivery systems, such as that of the US Postal Service or other private sector entities like FedEx, DHL, UPS, and Wal-Mart. There is no shortage of ingenuity and creativity in communities across the country, but the generation of ideas should take place now, in advance of an event, and feed into planning efforts that should also be ongoing currently, at the local level.

Second, although our epidemiological investigation capabilities (and supporting laboratory capacity) are in better shape than they were five years ago, our bio-surveillance capabilities still need work. An effective national bioterrorism surveillance system would: allow public health and emergency managers to monitor the condition of human, livestock, and crop populations; track outbreaks; and act as an alert in the event of an attack. (This list is merely illustrative, not exhaustive). Non-traditional first responders, such as agricultural services inspectors, entomologists, and veterinarians, must have a seat at the national security table, and their expertise must be lashed up and fed into the broader surveillance effort. Moreover, since "bugs" know no borders, partnerships at the international level are important, and the United States should continue to work with the World Health Organization (WHO) to monitor infectious disease trends and outbreaks. Similarly, with US military services deployed around the globe, our military medical organizations may provide us with a sentinel system to monitor a multitude of health environments and serve as an early warning system.

A holistic perspective on preparedness for bio-terrorism and pandemic flu also requires consideration of the pre-hospital piece of the puzzle, that is, emergency medical services (EMS).[2] Here again, surge capacity is an issue. More often than not, EMS systems in this country operate at close to capacity on a day-to-day basis. A large-scale event, particularly a sustained one, would tax the majority of our EMS systems beyond their ability to respond unless we commit now to focusing, with unprecedented determination, on the ramp-up from the ordinary to the extraordinary. In connection with such efforts, perhaps we should examine the merits of creating an equivalent to the Emergency Management Assistance Compact (EMAC), not only for EMS but also for the public health system more generally. In

any case, expansion of operational capabilities should not take place in a vacuum – supporting policy and doctrine must be developed concurrently. Continuity of EMS operations may not be assured if EMS providers fear that their own families may not be taken care of during extraordinary times. This issue resonates across the board with all first responders, and highlights the need to think through carefully the implications of allocating and prioritizing the distribution of finite amounts of vaccines, antidotes, and the like.

A Goldwater-Nichols Equivalent for Public Health

Honing our technical capacities alone will not be enough. Intangibles are an equally important element of the equation. Specifically, a culture of preparedness that is common to the health sector and the national security sector alike, as well as beyond, is the glue that will hold together the sprawling enterprise that is our national preparedness and response system. Cultural change is notoriously difficult to bring about, but it is absolutely essential that we cultivate the mindset that will support the convergence that has taken place on the ground, between public health and national security. The two are now inextricably and indisputably intertwined, and only if a genuine culture of "jointness" prevails will we be able to achieve in practice the requisite reforms to our system, be they structural, procedural, budgetary, programmatic, or policy-related. Notably, this is a two-way street: the national security community needs to be well versed in public health matters where the two domains intersect, just as healthcare providers and medical experts need to be fluent in the language and practice of national security.

Put another way, perhaps a Goldwater-Nichols equivalent is needed for the homeland context and for the public health and medical arena in particular. In recent testimony before the Senate Homeland Security and Government Affairs Committee, during their after-action hearings on Hurricane Katrina, I emphasized that the challenge of successfully executing interagency coordination is age-old and that, although we probably should never transpose wholesale a military model into the civilian context, there is substantial merit in looking to the military context given its success in institutionalizing the concept of jointness.[3] As you know, the 1986 Goldwater-Nichols Act unified and streamlined the defense structure, and realigned budgets accordingly. Over time, greater cohesion has resulted in heightened effectiveness. A Goldwater-Nichols equivalent for the homeland should not be limited to the federal level, but should apply also between and among the states themselves.

Performance Metrics, End-States, and Budget Realignment

As a starting point, better and sustained coordination (at all levels) between the Departments of Health and Human Services, and Homeland Security, is sorely needed. By way of illustration, both HHS (the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the National Institutes of Health) and DHS are directing substantial funds towards bio-terror and pandemic preparedness and response initiatives. Yet, these monies are not being distributed or allocated according to a streamlined and well-coordinated process. Instead, there is a multiplicity of funding sources and the left hand does not always know what the right hand is doing at least in so far as grants are concerned. An outcomes-based system, with built-in performance measures and metrics, would go a long way towards remedying the present situation. By focusing on end-states and capabilities, just as the outcome-oriented NPG scenarios guide us to do, and by giving life to the adage "what gets measured gets done," both our goals and the paths to achieving them would be clarified. Realignment of budgets, and coordination of the various departmental and agency funding streams would follow, as a logical corollary. This level of organizational rigor would promote an efficient and effective use of our limited resources. It would, after all, break the bank if we were to try to fight each "bug of the day" with vaccines, antidotes, and prophylactics.

A more harmonized approach at the federal level would also serve the nation well. As things now stand, no common threat assessment exists in the form that is truly needed. This is a disservice to us all. At the very least, the various departments concerned should be looking to one another to remain informed, and relevant information should be disseminated to the frontlines, where it may be acted upon.

A Regional Approach

It is on the frontlines that the bulk of decisions during an event will, and should be, made. For this reason, we need to build capacity in the field, and regionalizing our national preparedness system – the linchpin that connects all of the elements of our preparedness and response – is, to my mind, perhaps the best way to build the robust capabilities that we seek to achieve on the ground. Co-locating Regional Health Administrators with regional components of DHS and field components of DoD as well as other stakeholders, including representation from the private sector, would foster synergies and forge strong partnerships before disease or disaster strikes. In turn, these bonds would (among other things) facilitate the management and

deployment of the SNS and the NDMS. Encouragingly, it appears that DHS is, in fact, expecting to establish a planning mechanism through joint field offices that would serve as a framework for coordinating response for all levels of government (including any military joint task forces that may be established), non-governmental organizations, and the private sector.

A muscular regionalized system serves the best interests of the states and their governors by providing the latter with an all-purpose federal point of contact that is well-versed in the particularities of a relevant area. Conversely, from a national perspective, regionalization offers a means of unifying planning, training, and exercising efforts – a prerequisite for identifying and developing needed federal, state, and local capabilities and capacities. Looking forward, HHS and its regional coordinators should be consistently plugged into DHS' exercise schedule, and future exercises should specifically focus on bioterrorism and pandemic influenza scenarios. At a time when the convergence of public health and national security is plain, it is at our peril that we allow any disconnect to persist. It should also go without saying that after-action "hotwashes" should be conducted to identify lessons learned during exercises, and that such lessons should then be fed back into the system in order to prevent the same mistakes from being made once again as well as to benefit those who were not party to the actual exercise.

Taking a regional approach to hospital preparedness would also be valuable, though most hospitals are not now regionally oriented in their planning, activities, and outlook. Exceptions to the rule include the National Capital Region (NCR) and North Carolina, where real regional medical capabilities exist in the form of mobile hospital capacity. The lessons learned from these experiences should serve as a model for the country as a whole, demonstrating the benefits of joint planning and exercising between and among hospitals at the regional level.

Although limited regional surge capacity remains a significant problem, it is undeniably mitigated by surge protection – a strategic solution known as "community shielding." A recent study of the NCR revealed that many area residents would abandon their protected home and work environments during a contagious epidemic, despite government instructions to shelter-in-place. However, if there is an effective mechanism for community shielding through distribution of food, water, medication, and information to those who need it, those potential evacuees would in fact follow

instructions, thereby enhancing community resilience by remaining safely in their homes and localities until the regional threat has abated.[4]

Key Partners

In our zeal to "get it right" when it comes to preparedness for bioterrorism and pandemic influenza, we should take care not to stretch too thin those assets that have proven their worth time and again in many and varied contexts. Our military forces proved to be able and responsive in the aftermath of Katrina and, as the saying goes, "no good deed goes unpunished." This month alone, the National Guard has been assigned a significant role in furthering border security as well as implementation of the National Strategy for Pandemic Influenza. While the National Guard brings valuable skill sets to domestic needs, the Guard has a dual character and mission, and its war-fighting aspect should be respected and retained. Moving forward, it will be important to bear this bigger picture in mind, and exercise caution and balance accordingly, when drawing and planning to draw on such treasured and proven national resources.

The nature of the challenges before us dictate that everyone be involved in preparing for them. It is no exaggeration to suggest that this is not only a community-wide responsibility, but also an individual one. Families, schools, places of worship, and business – all have an important role to play in containment of infectious disease, and all must be well integrated into the operationalization of relevant strategies and plans. Personal preparedness will take on a much greater importance in pandemic influenza than even natural disaster. Ultimately, it will be up to individuals to take personal responsibility for their own support, namely enough food and water should they be required to stay at home. Framing expectations in advance will be necessary to avoid hysteria. Just last week, Buncombe County, North Carolina, provided an excellent example of a local physician and the local media partnering to manage expectations and to let people know that they will not be able to rely on state and local governments, in particular health departments. There, a small newspaper in Asheville published an editorial piece written by the doctor in question, stating that the federal and state governments have outlined what they will need to do to respond to pandemic flu, but in the final analysis, "[o]ur job as citizens is to be informed and prepared."[5]

Preparing for bioterrorism and pandemic influenza also requires robust partnerships between the private and public sectors. At the same time, each sector must do its

utmost to put its own house in order. While a majority of U.S. businesses have expressed their concern about pandemic flu, only a much smaller fraction have actually done robust continuity of operations planning, which is crucial to maintaining critical infrastructure operations and services in a crisis.[6] During and after Hurricane Katrina, however, the private sector was a tremendous source of both materiel and expertise, including logistical support. Industry, and particularly "Big Pharma," offers a wealth of knowledge that must be thoroughly tapped for present purposes. With proper incentives, the private sector's research and development capacity, and production capability, could be fully marshaled and harnessed for national ends, with striking results. Incentives offered by Project BioShield have been insufficient to garner the full support of investors, whose support of the fledgling countermeasure industry is critical. To the extent that prevailing legislation and frameworks come up short in their incentive structure, it is crucial to complement those measures with needed new ones, and to re-structure and redesign existing mechanisms in a more rational, market-oriented manner that effectively addresses potential deterrents such as liability issues, and profit and cost factors. The "DARPA-like" proposed Biomedical Advanced Research and Development Authority, contained in bill S. 2564, could serve to assist companies in crossing crucial thresholds and allow relativelyadvanced products to actually reach the marketplace. In order to make progress on this front, it is imperative that industry perceive the federal government to be a reliable partner in this endeavor.

Conclusion

As we strive to create a performance-based, outcomes-driven preparedness system that is responsive to all hazards but also to the unique needs under study at this hearing, it must be remembered that policy without resources is rhetoric. Though redressing a number of the gaps and shortfalls in our preparedness posture identified herein will turn less on matters of financing than on other issues, in some cases funding will be essential to realizing requisite unique capabilities. The SNS is but one area which would benefit strongly from an injection of new monies, specifically to "plus up" its contents. Not only are the caches for that "very bad day" insufficiently supplied, but our current stock of basic but fundamental items such as facemasks and ventilators is simply not adequate, and the same is true of certain drugs and countermeasures. Dual-use elements that are also instrumental to the provision of "ordinary" or day-to-day medical care should be viewed as sound investments that will yield significant rates of return – an important fact and a feature that is consistent

with a system founded on accountability and on end-state capabilities and capacities. Throughout, it bears remembering that what gets measured gets done, though we need to make sure that we are always measuring what matters.

The Subcommittee should be commended for its determination to study the difficult issues before us today. Tempting as it might be to alter focus, and direct time, money, and energy exclusively to other less complex challenges that might be easier to master, it would be a mistake to do so. The scale of the challenges under examination today is undoubtedly large, and even an entity the size of the federal government cannot tackle these issues alone. Northing short of a highly sophisticated, multifaceted, and integrated response will suffice – but I am confident that the creativity and resolve demonstrated by the American people so often in our history will once again serve as a solid foundation upon which to build as we endeavor to meet that bar which has been set so high. Thank you and I would be pleased to try to answer any questions you may have.

[1] Testimony of Frank J. Cilluffo, "The Threat of Bioterrorism and the Spread of Infectious Diseases," Before the U.S. Senate Committee on Foreign Relations, September 5, 2001.

[2] For a more detailed examination of EMS issues, see: Homeland Security Policy Institute (HSPI) Issue Brief, *Back to the Future: An Agenda for Federal Leadership of Emergency Medical Services*, May 2, 2005.

[3] Testimony of Frank J. Cilluffo, "Hurricane Katrina: Recommendations for Reform," Before the Senate Homeland Security and Government Affairs Committee, March 8, 2006.

[4] M.T. Williams, G.B. Saathoff, T.M. Guterbock, A. MacIntosh, and R. Bebel, *Community Shielding in the National Capital Region: A Survey of Citizen Response to Potential Critical Incidents* (Final Report, Volume 16), September 2005, http://cipp.gmu.edu/archive/Vol-16-%20Community%20Shielding%20in%20the%20NCR.pdf.

[5] Marilyn A. Roderick, "As threat of the avian flu looms, one question remains: Will we be ready?" *Asheville Citizen-Times* (May 16, 2006). See also David Heyman, *Model Operational Guidelines for Disease Exposure Control* (Center for Strategic & International Studies, 2005), at http://www.csis.org/media/csis/pubs/051102_dec_guidelines.pdf [offering detailed guidance on non-pharmacological measures that public officials and individuals could take for protective purposes].

[6] David Brown, "Business Plan for a Pandemic? Most Firms Haven't Prepared for Possibility of a Global Outbreak," *Washington Post* (May 2, 2006), p. D1.