

Witness:

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Testimony

Thank you for the opportunity to participate in the July 14, 2005 Roundtable entitled "When Terror Strikes – Preparing an Effective and Immediate Public Health Response", sponsored by the U.S. Senate Committee on Health, Education, Labor and Pensions, Subcommittee on Public Health Preparedness. Your continued, bi-partisan leadership on these critical issues of national security is to be commended. I am pleased to respond to the Subcommittee's written questions.

Each of the three questions addresses critical aspects of biosecurity. There has been some modest progress in each of these areas in recent years, but in spite of earnest efforts by many hard working government officials, the nation remains largely incapable of mitigating the consequences of a serious bioterrorist attack, or campaign of attacks or of marshalling a coherent response to a natural pandemic. The disappointing pace of advancement is due in part to the technical and managerial challenges involved.

More significantly, the strategic significance and urgency of the biothreat has not been grasped or conveyed in ways that make possible the political and budgetary sea changes needed to establish the priorities and policies and build the new systems we will need – both in the US and internationally – to mitigate the death, suffering and social and economic disruption that will come in the wake of a large, lethal and fast-moving epidemic designed and perpetrated by a thinking enemy or by mother nature.

There is a pressing need to develop a long-term U.S. biosecurity strategy, a "vision of victory" which would, if implemented, afford the nation protection against destabilizing epidemics. This will necessarily be a long-term project given the complexities of the threat and the scope of the systems we must prepare and build. In my written comments, I will try to address both strategic goals and more tactical, near-term priorities.

(1) What additional incentives or other measures will ensure timely availability of sufficient amounts of effective biodefense medical countermeasures, and is the cost of such incentives acceptable?

The U.S. should establish the strategic goal of radical accelerating the development of vaccines and medicines for the prevention and treatment of infectious disease as a top national security priority. If the current timeline of countermeasure development is maintained (approximately 10 years for small molecule drugs and 7 for biologicals), the country cannot possibly afford to maintain anything resembling an adequate national stockpile of critical therapeutics against the array of potential bioweapons, nor we will have the capacity to "surge" production of needed medicines and vaccines in times of crisis, because the cost of maintaining adequate "warm base" production capacity will prove prohibitive. Furthermore, the threat of bioengineered weapons – and the age of

such weapons is upon us, not a futuristic fantasy – will require the ability to rapidly create countermeasures to unanticipated pathogens.

The extraordinary advances in biological science that are now underway is such that the goal of radical acceleration of drug development is an ambitious, but plausible project, with huge payoffs for reducing the costs of health care, spurring medical innovation and addressing the burden of infectious disease in the developing world . Such a goal would require a sustained commitment on the part of the US government as well as innovative leadership, but is, in my view, absolutely essential to US national security.

Tactical, near-term goals

Consider new funding approaches to support the near-term development of specific countermeasures and to promote the strategic goal of accelerating drug and vaccine development generally. More specifically, Congress could consider:

- Funding mechanisms to support the early development phase of countermeasures (the “valley of death”).
- Creation of a “BioDARPA” that would invest in transformational bioresearch. Such research would be “project driven” and linked to identified national needs.
- Exploring ways to encourage the biopharma industry to invest in anti-infective R&D and to pursue accelerated drug development. It is important to understand that the biopharma industry is abandoning anti-infective R&D generally – new antibiotics and antivirals and new vaccines are simply not popular investments because they do not produce returns on investments comparable to other drugs. These financial realities, the growing problem of antibiotic resistance, and the enormous burden that premature mortality due to infectious disease levies upon the developing world are going to require that governments develop innovative approaches to anti-infective medicines and vaccines, quite apart from the imperative of creating countermeasures against biological weapons. The Sementech model that was used to ensure US capacity to manufacture essential microchips may be worth examining, as are suggested schemes for creating guaranteed markets for certain vaccines etc. [See, for example, “Making Markets for Vaccines – Ideas to Action”, Center for Global Development, 2005.]
- Fixing the liability problem now. Most companies will not even consider countermeasure development unless they are shielded from the potential risk associated with a vaccine or medicine that cannot be tested in large clinical trials and may be used for the first time on large, heterogeneous populations in time of grave medical need. How and whether liability concerns are handled in Biosheild II will be interpreted by the industry as a bellwether of the government’s commitment to securing effective countermeasures and will be seen by the public as a signal of the government’s faith in these products. Some federally backed compensation scheme to protect patients injured by countermeasures found faulty (through causes other than negligence) should also be enacted.

- Reviewing and clarifying the HHS/DHS process for declaring a material threat and deciding what to purchase with Bioshield funds. The current process is mysterious, disjointed, slow and inefficient. “Splitting the baby” between DHS and HHS seems unnecessarily complicated, is causing long delays and discouraging private sector participation. Red teams or some other oversight of the threat assessment process and of HHS Bioshield acquisition process should be instituted. Expert users (e.g. experienced clinicians and hospital administrators) should have a role in determining stockpile ingredients. Agencies must be assigned appropriate resources and expertise to manage these important programs and it should be clear which executive branch programs and political appointees are accountable for progress. Without a coherent and fairly transparent process for assessing threats and determining government investments, biopharma will not invest in countermeasure R&D and the public will not be persuaded that public funds are being well used.

- Incentives to spur investments in the development of anti-infective medicines and vaccines are almost certain to be an essential component of an effective biodefense. I do not think it is possible to produce the countermeasures needed to protect the country without the active participation of the biopharma industry – they are the ones who know how to make drugs. The cost of effective incentives will be high. If such incentives are seen as an indirect tax on health care, or are extracted from the already inadequate HHS and DHS budgets, they are likely to be unpopular with much of the public. One possible approach to allaying such anxiety is to “take” funds for countermeasure incentives from the DOD budget – any zero sum budget calculations could be traded against other national defense purchases, not extracted from vital, highly pressured health care budgets. Eventually, it will be necessary to recognize that funding countermeasure development – and most of the nation’s biodefense needs - must be accounted for as essential national security investments. It is unlikely that the scope of investments and scale of new systems that will be needed to achieve biosecurity can be marshaled unless and until such expenditures of talent and treasure are recognized as central to the nation’s security. The question is whether the country will reach this recognition before a destabilizing attack or natural pandemic occurs. The record of achievement in preparing for pandemic influenza is not encouraging.

(2) What is necessary to build and maintain a robust national public health infrastructure to meet future biodefense requirements?

For the past four years, the US has spent approximately \$1B annually on improving “public health preparedness”. By all accounts, progress has been modest. Here too, there is a need for a strategic vision of what capacities we are trying to build, a clear sense of priorities, and a coherent approach to match federal investments with realistic costs. It is essential to reduce the current confusion about which federal agency is in charge and to ensure that the accountable federal and state offices have the resources and technical staff sufficient to manage the programs under their purview.

It would be useful to clarify the notion of “public health preparedness” by specifically

identifying a few critical epidemic response capacities and considering how these might be best achieved. The preparedness demands imposed upon state and local public health departments, and upon CDC, have proven unrealistically ambitious given the resources made available and the often competing priorities of Governors and local officials. I offer the following suggestions for your consideration:

Realistically assess the existing limitations of public health agencies; acknowledge the scope of what we must do

For the most part, the 5000 different “public health agencies” do not spend much time or resources on the type of tasks that will be essential to responding to bioterrorism or to natural epidemics. This is not a criticism, it is simply reality: large scale outbreaks of infectious disease have not been a big problem in the past 50 years. It will not be possible to create the ‘necessary infrastructure’ of epidemic management by tweaking or upgrading current structures. The nation is going to have to build whole new systems to manage epidemics. The sooner this is recognized and we start to plan these systems and establish priorities the less time and money will be wasted, the sooner we will begin to have a rudimentary response capacity and the more likely it will be that such investments reap peacetime, “dual-use” benefits.

Epidemiological analysis; advice to decision-makers; communication with the public

No entity other than governmental public health agencies is likely to have the authorities or access needed to collect and analyze information essential to managing a large, fast-moving epidemic. At present, few agencies have the necessary talent or the tools or the training to fulfill these critical tasks, upon which will depend all decision-making from the local level to the national command authority. Communicating with the public is also a task that must be fulfilled or greatly aided by public health officials. It may make sense to assign a high priority to ensuring that all state health agencies meet certain standards of personnel training and are equipped with adequate information management systems and tools to carryout these critical functions.

Invest in training and credentialing of public health officials.

It is important that any such training be appropriately focused. The current emphasis within most schools of public health is on research techniques, not public health practice. For training investments to pay off there would have to be a new commitment to “professionalizing” public health training. It would make sense to make government service a condition of support for individuals participating in such programs and to require participating schools of medicine and public health to develop the appropriate curricula and practicum experiences.

Build the electronic information systems necessary to ensure situational awareness during epidemics

Creating a national electronic health network within the medical care community is an essential component of a robust public health information network. President Bush has

cited such systems as a highly desirable goal to improve medical care quality and to reduce health care costs – but current plans call for implementing such systems over the next decade, with minimal federal investments. The US should make the implementation of an integrated electronic health information highway a top national security priority and commit to having such a system in place within the next five years. In the near-term, consideration should be given to how outbreak management “modules” of a comprehensive medical and public health information system might be designed and piloted, with the goal of implementing such modules in all states within 3 years.

There is a well-recognized and urgent need to build the electronic information systems needed to manage large disease outbreaks. No public health agency has the know-how or resources to design and implement such systems on their own, nor does CDC have this expertise. Such a project must be driven by the federal government with significant support from the private sector and from the user communities. Functionally, such systems must link health care providers – hospitals, clinics, HMOs and individual clinicians – with public health agencies. Public health authorities must have the capacity to rapidly collect and analyze data from multiple sources – especially from the health delivery organizations and from clinicians - in near-real time and to interpret such information for clinicians, the public and elected officials.

Protecting the well: mass prophylaxis, mass immunization

A key provision to any solution to the problem of achieving rapid distribution of drugs and vaccines to large populations in time of crisis is the active support of the nation’s governors and mayors. They must embrace the importance and urgency of this difficult task and be willing to expend the personal time and attention needed to bring together parties within their own jurisdictions and to broker regional solutions. Anything Congress or the Administration can do to signal and emphasize the importance of such leadership would be useful.

It could be useful to “unload” some of the burden from public health agencies by assigning more operational responsibilities to the health care organizations and other organizations in the private sector. Hospitals and HMOs generally have more institutional capacity – more people, more resources, more administrative skills, more agility - than most public health agencies, in spite of the problems and financial pressures which besiege the health care delivery sector. Moreover, dispensing drugs and giving injections is what hospitals and health care delivery companies do every day. Many state plans call for massive recruitment of local health care providers to implement mass prophylaxis or mass vaccination. It may make sense to devise incentives or to obligate all or some hospitals and HMOs to take a more proactive leadership role in planning and executing such activities. For such an approach to work, it would be essential to provide appropriate compensation to the participating health care organizations.

Also, many supermarkets, pharmacies and wholesale discounters (e.g. Costco, etc.) routinely deliver flu shots and other immunizations. Research by Onora Lien and others at the Center for Biosecurity has shown that these companies cover a huge population

nationally, are in every neighborhood, maintain the infrastructure needed (parking lots, electronic registration systems, registered pharmacists and nurses) to attend to large populations, and are willing and eager to help deliver care in times of emergency. Such innovative approaches should be aggressively explored. It is hard to imagine this happening unless such responsibility is clearly assigned within the federal agencies.

Care of the sick during epidemics

Care of the sick in the wake of a bioattack or natural epidemic is obviously key to mitigating death and suffering and to communities' ability to recover. Inexplicably, this aspect of bioterrorism response has been badly neglected. The monies and federal staff resources dedicated to hospital preparedness are minimal and progress is even more limited than in the public health arena. It is unclear if HHS or DHS is responsible for this sector, there is no identifiable political appointee in charge and there have been few efforts to reach out to hospital or clinical leaders and professional groups.

The roles and expected response capacities of the medical sector must be examined and clarified. It is impossible to imagine any effective mass casualty response that is not organized on a regional basis, yet there is no "organizing authority" charged with creating such regional collaboration or coordination. Here again, governors and mayors could play key roles, as could some major academic medical centers and professional organizations. My colleagues and I would be happy to provide more specific thoughts on medical preparedness if this would be helpful.

(3) What is necessary to protect our food supply and agriculture from biodefense threats?

Government must exercise – and be seen to play – the role of honest and reliable protector of the US food supply

An attack on agriculture or the food supply could have significant economic and psychological consequences, but is not likely to be a strategically destabilizing event. The consequences of such an attack would depend greatly on the government's response. To that end, it is imperative that the US government be seen as an honest broker in these matters. The recent handling of reports of BSE in American cattle – at least as is portrayed in the press and in professional journals – is sending the signal that the government may not be telling the truth in a timely fashion. Such impressions could reap a harsh reward if the government finds itself in the position of trying to persuade citizens and international consumers that the danger from a real attack are over or contained. Scientifically based surveillance systems are essential to ensure the safety of the food supply and the financial competitiveness of US agriculture. Such systems should be developed and deployed now. This will require the USDA assuming an active oversight role and being seen as a reliable overseer by the public.

We need a plan for responding to the most likely scenarios

Much was learned from the 1999 outbreak of FMD in the UK, but it is not clear that these

lessons have been incorporated into US response plans. Roger Breeze has presented a serious proposal that might greatly limit the adverse consequences of an attack using foot and mouth disease. This plan and other alternatives should be critically examined and red-teamed.

Thank you for this opportunity to respond to the Committee's questions. I look forward to working with you and your staffs on these important issues.

Yours truly,

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