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Department of Homeland Security Role in Bioterrorism Countermeasure R&D
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Mr. Chairman and Members of the Committee, it is an honor for me to testify before you today regarding the role of the Department of Homeland Security in launching, managing and sustaining an ambitious science and technology research program for new countermeasures against weapons of mass destruction. My comments will focus particularly on how the Department's leadership role can obtain diagnostics, drugs and vaccines to protect our nation from a bioterrorist attack, but many of these observations are relevant to the other WMD threats.

The Bottom Line

As a serial entrepreneur and now a venture capitalist, let me focus on the bottom line: the Nation will only be successful in obtaining the bioterrorism countermeasures it needs if the new Department is able to engage the enthusiastic participation of the biotechnology and pharmaceutical industry. I can state unequivocally that the conditions are not in place to accomplish that goal today.

First, dramatic organizational changes must take place in the way we prioritize our needs: that is the great opportunity afforded by the creation of the Department under discussion today. The Department offers a chance to develop a fundamentally new approach for engaging the private sector in this effort. Current DOD and NIH bioterrorism countermeasure efforts are submerged in large agencies with diverse agendas. The new Department can bring a single-minded focus on development of the highest priority countermeasures and will have the stature to make sure public and Congressional interest does not flag during the long development times for many of our needed measures.

Second, the Department must signal private sector enterprises and the vast capital markets that support them that we will create a meaningful market for successful new technology that addresses our highest priority needs. While the discussion of particular incentive structures is not the topic for today, it is important that the Committee understand the fundamental difference between what drives our remarkable high-technology and biotechnology industries and the traditional defense industry. I know that some of the points will be familiar to Senator Lieberman, whose insightful S. 1764 provides for sound, innovative incentives that require serious attention.

Perhaps the Committee should direct the Department to work with appropriate experts to optimize the incentives and respective roles that will produce the public-private partnerships we need and to make legislative recommendations. I would anticipate that we need different groups of experts to address these incentive issues for biological, chemical and nuclear threats because the technical and economic challenges are different.

High-tech and Biotech Companies are not built to do Contract R&D

A recent report highlights the trillion dollar contribution to our Nation's GDP and the 27 million jobs from venture capital-backed companies such as Apple, Microsoft, and Amgen and FedEx. Currently there are over $75 billion allocated to venture capital funds in the United States that are available for investment in companies which offer the potential for explosive growth by delivering products into large markets with clearly understood unmet needs.

Venture capitalists do not, as a rule, invest in companies with business models such as professional services firms or companies aiming to build a business based on contract R&D at 15, 20 or even 30 percent gross margins. We aim for our companies to produce products based on defensible intellectual property which have the kinds of margins seen in truly innovative software, pharmaceuticals, and electronic devices. Year in and year out, through the natural cycles of technology, this is a proven recipe for creating enormous value for consumers and investors.

That is why I am so concerned about the current shortsighted focus on getting a bunch of R&D started on bioterrorism countermeasures without giving full attention to the actual products we need to build and the market forces that will get

them finished and deployed and sustained.

The Department of Homeland Security can address this problem

Centralizing the authority in the Department for setting priorities, funding solutions, and managing incentives is the first and most important step. My own experience trying to find the "go-to guy" responsible for specific bioterrorism countermeasures reinforces what you have seen in report after report (such as Hart-Rudman, Gilman, and the Defense Science Board) documenting the appalling division and duplication of responsibilities among dozens of silos in the Departments of Defense, Health and Human Services and elsewhere throughout the government. It is impossible to locate the **customer** for any significant, long-lead time technology that might just save our Nation from several of the highly likely attack scenarios.

First, we need a national strategy for Homeland Security and the new Department should play the central role in its creation and maintenance. I would be concerned about anything that causes confusion about who is in charge, as might happen if we create a statutory Office for this purpose in the White House. It could be seen as yet another silo, one more voice in the cacophony attempting to perform "coordination" among disparate agencies. Homeland Security is surely the most basic component of national security. Let's make the National Security Advisor and the President accountable for ensuring that the new Secretary has the cooperation he needs. There seems to be a myriad of new panels and committees being proposed. Strategy and work groups should be broken down by the nature of the threat, not according to the government's org chart. The technical challenges, expertise, and private-sector relationships are different for chemical, biological, nuclear and cyber threats. I can say for sure that we need one high level decision-maker and one high level expert panel devoted exclusively to the problem of biological threat and response if we are to optimally engage the private sector. Both should reside in the Department, freed of historical institutional biases and allowed to focus on results and not process.

The Department must be able to work effectively with both HHS and DOD on science and technology related to its goals, and we should be bold in taking steps to move entire programs into the new department, especially where there is a history of poor coordination and duplication and especially where we need to engage the private sector. The Department can and should be a model for effective public-private partnerships. The Department's leadership role should be clearly extended to include all of the research specifically addressing the bioterrorism threat conducted anywhere in the Executive Branch.

Strong engagement with the Department of Defense is essential

The failure to seriously address integration of homeland security with the Department of Defense efforts is a glaring omission in the draft legislation I have reviewed. Blue ribbon panels have been especially critical of DOD's productivity and preparedness for biothreats relating to the homeland. In our darkest reflections on the new reality, we know that the military will be required to enforce any meaningful quarantine around a bioattack with a transmissible agent. Think about it: protection of our warfighters engaged in a homeland defense operation is inseparable from protection of civilian responders and the general population. As we learned so clearly in the Swine Flu episode in the 70's, the specification, manufacture, distribution and deployment of a biological countermeasure (the swine flu vaccine) must be integrated in a seamless policy. In retrospect, it was the right thing to stockpile the vaccine, but we should have waited with a hair trigger for more information to begin immunizations.

Homeland security and the Food and Drug Administration

Another key relationship for the new Department that is getting too little attention is that with the FDA. As a wealthy society in peacetime, with strong sense of accountability for everything related to health, we have evolved a highly conservative posture towards regulating medical products. Our society continuously engages in a constructive dialogue about how to balance risk and benefit in most settings, but there is a clear and different need for leadership regarding our risk posture for biodefense countermeasures. In the setting of moderate threat, we will likely want to offer the public vaccines or drugs that carry the benefit of full FDA approval from the perspective of this very risk-averse posture. But just as generals must make difficult trade-offs in time of war, some threat scenarios require that the Secretary commission, stockpile and be prepared to deploy biological countermeasures that carry very significant risk to individuals. We can give

him the authority to have us prepared for worst-case scenarios without weakening our strong peacetime regulatory systems.

Meaningful countermeasures are definable and achievable

The new Department should reject the notion that there are so many biothreats imaginable that countermeasures are doomed to fail. We **can** identify the highest risk agents for the near and intermediate time frame, based on the biology and technical challenges faced by our attackers. Even though HIV has remained elusive, most concerted vaccine development programs against important natural agents have succeeded! Drugs and new approaches to helping the immune system offer additional opportunities.

How did these successful vaccines come into being? In almost every case, the basic science was supported at or by our extraordinary National Institutes of Health. And without exception, the applied research necessary to translate these basic findings into workable, safe, effective manfacturable biologic products was carried out by pharmaceutical and biotechnology firms that were driven to create value for their shareholders by pursuing large market opportunities for high-margin products.

We should also acknowledge that there are categories of threats that are difficult to address with long-lead time agent-specific countermeasures. An example would be novel genetically engineered pathogens for which we need novel and powerful new approaches. Senator Lieberman has pointed in S. 1764 out that we also need to stimulate creation of rapid-reaction research tools so that we might someday have the power, in the middle of the epidemic, to develop and deploy completely new countermeasures.

Are the markets too small to motivate private investment?

Some of the countermeasure priorities to be set by the new Department will have important beneficial uses against natural infections and diseases. A broad-spectrum antibiotic needed for plague or tularemia could save lives in the hospital from multiple-resistant infections. Gene chips deployed as an early warning system for bioattack could be designed to timely register the appearance of naturally occurring pandemic influenza, an inevitable phenomenon which has the potential to cause more damage to our population than many man-made epidemic scenarios. Contract R&D via the very useful SBIR process or DARPA's remarkably enlightened procurement mechanism is an ideal way to stimulate such dual (beneficial) use technology.

But when Government is the only natural customer for products that require long-term, high-risk applied research and development, the government must find a way to effectively engage its suppliers. I am thinking of vaccines to protect against Ebola, for example. We need a new model, without the parasitic dependency fostered by current DOD procurement. A properly empowered Secretary in the new Department can engage the community of bioinnovators and they will work with him to create this model.

Compared to their primary markets in the civilian health care system, biodefense markets may look small, but I think this is due to our failure to really grapple with what is at stake. A moderate earthquake in Taiwan on 9/21/99 shut down that country's high tech industry for 10 days. As a direct result, dozens of our Silicon Valley companies missed their quarterly earnings because shipments of critical components were delayed. Imagine how long it will take to get those chips, motherboards and displays to build our products if five confirmed cases of smallpox occur in Taiwan next month! A requisition for two hundred million doses of smallpox vaccine is ten times too small to protect our economy from the threat of an attack on our trading partners! Our allies and trading partners have an equal stake in this deadly game and must be pressed to carry their part of the cost. The Homeland Security Department needs to be able to reach out and make this happen as well.

Background as a biomedical entrepreneur

My comments here are based on my experience as co-founder of Affymax, co-inventor of the technology underlying the Affymetrix GeneChip ™, as founder of Aviron, a venture- backed vaccine discovery and development company recently

acquired by MedImmune, and now a partner at Alloy Ventures, a venture capital fund investing in entrepreneurs building early-stage companies in information and communication technology and the life sciences. I have served as a member of the Executive Committee of the Biotechnology Industry Association and am currently working on a project with Business Executives for National Security focusing on policy issues discussed in these remarks.

Finally

I would like to compliment this Committee and the Chairman for vigorously and sincerely taking on the challenge of designing our new homeland security structure beginning immediately after September 11th. Your efforts here will undoubtedly have an enormous impact on our ability to carry on with our lives in spite of the new threats.

It is essential that the new Department be established, that it be forcefully led, that it have the tools it needs to be effective and that it is held accountable for preparing us for a bioterrorism attack. I am sure that the private sector will play an important role in its success.