Sen. Sheldon Whitehouse Institute for Immunology and Informatics 6th Annual Vaccine Renaissance Conference October 15, 2012 As prepared for delivery

Thank you, Dr. De Groot and Dr. Spero, for your kind words. Under your leadership, the Institute for Immunology and Informatics has emerged as a leader in the fight against infection and disease. That means not just research and development of newer, safer vaccines, but also advancing new methods of discovery and disseminating the tools developed here at URI across the health care field.

iCubed has promise for the 21st-Century Rhode Island economy. Your "gene-to-vaccine" approach could foster a variety of research, medical and biotech enterprises here in the state, and your training programs for scientists and entrepreneurs reflect that goal.

The Vaccine Renaissance Conference, now in its sixth year, is an important gathering of national bioinformatics and immunology leaders. It is a chance for experts to present their research, and exchange ideas about important developments in vaccine science. I am proud that this event has found a home here in our state at the University of Rhode Island.

This morning we examine the critical biodefense issues facing the medical research and national security communities.

As you all know, in biodefense our national security and public health are fundamentally interdependent. The Commission on the Prevention of WMD Proliferation and Terrorism concluded that terrorists are more likely to be able to obtain and use a biological or toxin weapon than a nuclear weapon. We are advancing the development of new vaccines and other medical countermeasures to combat biological weapons, but we have not adequately built up the capacity to rapidly develop and deploy such countermeasures during a public health emergency.

In short, we must not wait until the next disease outbreak or a mass-casualty bioterrorist attack to act. Our approach to biodefense must be proactive. The potential human cost of an outbreak or bioterrorist attack justifies a sense of urgency on these issues.

It is important for both medical and policy leaders to bear in mind the significant differences between naturally-occurring infectious diseases and biological and toxin weapons delivered in overwhelming infectious doses, making them faster-acting and more virulent. Vaccines designed for one will not necessarily be effective against the other. Protecting against both dangers requires distinct approaches and methods, as you will hear Joel McCleary explain in greater detail later this morning.

The Department of Health and Human Services plays a key role in funding biodefense innovators, supporting the development pipeline, and identifying solutions to our infrastructure challenges. It is important that HHS recognizes the unique challenges of biodefense in its programming and funding—and that it is given the tools to do so.

The federal biodefense effort spans many agencies, each with different resources, scope, and approach. This complicates strategic planning, risk assessment, and the procurement of medical countermeasures. Congressional oversight of this effort is complicated because the issue overlaps multiple committee jurisdictions. Coordination through all this complexity is essential.

As a member of the Senate Health, Education, Labor, and Pensions Committee, I worked to advance the efforts at HHS and across government to set organizational priorities, beef up research funds, speed up the medical countermeasures development cycle, and strengthen our response capabilities.

I have also sought to help clear a pathway for smaller, innovative companies to work with government to develop approved biodefense products. I know from working with Rhode Island companies, such as EpiVax, that it can be smaller companies who are on the cutting edge of new technological breakthroughs in biodefense. Epivax is working on re-engineering the vaccine development process to accelerate the speed at which government can respond to a biological attack or disease outbreak, so that vaccines can be immediately available after any outbreak, scalable from individual to large populations in a minimum amount of time, and carrying little risk of side effects. The success of this project would be, in my opinion, a game changer.

Innovation in this line of work is not easy or cheap. It takes incredibly smart, gutsy, and determined individuals to push forward a new idea and to find a way to make it a reality. That's why I support the Small Business Innovation Research and Small Business Technology Transfer programs, which have a long track record in helping small businesses leverage federal support into innovative new technologies. Big companies do not hold a monopoly on big ideas, and I am proud of the role these awards have played in fostering innovation in Rhode Island.

I will continue to support efforts to ensure that our research, development, approval and procurement processes make the most of the work of innovative companies that can make enormous contributions to our nation's biodefense security, even beyond the research phase through manufacturing and clinical testing.

I hope that along the way we can work together to strengthen the federal government's role in facilitating your work and encouraging innovation, and, in doing so, make progress toward protecting public health and our national security.

Thank you very much.