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Keynote Address on National Preparedness

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Thanks to the Harvard Medical School and sponsoring organizations for making BioSecurity 2003 possible, and to Ken Shine for inviting me to speak this morning. Biosecurity preparedness and response have become signature challenges of our times, and today's session provides an opportunity to review actions this Administration has taken in response to them.

Following as they did the terrorist attacks of 9/11, the anthrax incidents the following month sent two unambiguous messages: our society is vulnerable to bioterrorism, and we are not prepared. We did not anticipate the potential for delivery of a biological weapon through the U.S. Postal Service. During the intervening two years, important steps have been taken, not only to make the mail safe, but also to protect and prepare the nation for a much broader range of threats. Much remains to be done, but a substantial framework has been created that will make further action easier, and clear directions have been established to guide the next steps.

Not only are we concerned with more virulent or resistant strains of anthrax, but also with other pathogens defined by the Centers for Disease Control and Prevention as "select agents". The most virulent of these organisms, the so-called "Category A" select agents such as smallpox, plague, botulism, tularemia, and viral hemorrhagic fever represent the greatest bio-threats. We must not forget, however, that there is a long list of other threats -- chemical, radiological, nuclear, and others that are depressingly conventional -- for which we must also prepare and respond.

Under the strong leadership of President Bush, this Administration has taken dramatic and systematic steps to deal with all these threats.

On October 9, 2001 the President established, by executive order, the *Office of Homeland Security*, and asked Governor Tom Ridge to lead it. The new Office had a mandate to develop and coordinate the implementation of a comprehensive national strategy to secure the United States from terrorist threats or attacks.

Just over one year later, in an extraordinary re-organization of the Executive Branch, President Bush signed into law the "*Department of Homeland Security Act of 2002*" creating the *Department of Homeland Security*. The following January Governor Ridge was sworn in as Secretary of the new Department. A month later, all or part of 22 different agencies were united into the Department. With a budget of $30.4 billion for Fiscal Year 2004, the Department has access to the critical operational resources needed to manage both man-made and naturally occurring disasters.

The shape of the new Department, and especially its technical infrastructure and supporting research and development functions, was influenced by two important and timely reports. The first, "*Making the Nation Safer: The Role of Science and Technology in Countering Terrorism*," was prepared under the auspices of the National Academy of Sciences, and appeared in June of 2002. This report made numerous recommendations in nine areas related to terrorism and its effects, including human health and agricultural systems, and has been an invaluable resource for those responsible for assembling the new Department and its offices. The second report was prepared by a committee of PCAST, the President's Council of Advisors on Science and Technology, co-chaired by Floyd Kvamme and me. That report, "*Maximizing the Contribution of Science and Technology within the New Department of Homeland Security*," benefited from the leadership of PCAST member and former Lockheed Martin Chairman Norman Augustine, who also served on Governor Ridge's Homeland Security Advisory Committee.

Even as the new Department was coming into existence, its Transition Project Office worked with the Office of Homeland Security to produce a *National Homeland Security Strategy* that was subsequently followed by more detailed National Strategies for specific areas. Now that the new Department exists, the White House Office of Homeland Security has morphed into the Homeland Security Council, paralleling the National Security Council. General John Gordon serves as the Homeland Security Advisor to the President.

Given the organizational structure, an able management team, and a well-founded set of high-level plans and strategies, the next step, of course, is funding. Thanks to consistent, and, I should add, *persistent*, efforts by President Bush and key members of Congress, funding for bioterrorism research supported through the National Institutes of Health increased by nearly an order of magnitude over two years, from $180 million to more than $1.6 billion (the final figure is a Presidential request). Within the Department of Homeland Security, an additional $305 million has been appropriated for biological countermeasures. Altogether in fiscal year 2004, approximately $920 million are dedicated to science and technology in DHS, to fund a wide variety of programs, including:

- $88 million for the *National Biodefense Analysis and Countermeasures Center*—a "hub and spoke" system to increase the understanding of and improve measures against potential bioterrorism pathogens;

- $98 million for *Threat and Vulnerability Testing and Assessment* including $11 million for cybersecurity R&D;

- $75 million for the *Rapid Prototyping Program* to facilitate the rapid adaptation of commercial technologies for counter-terrorism measures by DHS and first responders;

- $70 million for the *Homeland Security Scholars and Fellows Program*, which will allow graduate and undergraduate students to pursue scientific studies in homeland security, and will fund the establishment of *Homeland Security Centers of Excellence* at universities across the country;

- $675 million for *critical infrastructure protection*, including research, development, testing, and evaluation of anti-missile technology for commercial aircraft;

- $134 million for the development of sensors and other countermeasures *to prevent the unauthorized transport and use of radiological and nuclear materials* within the
- United States;

- $40 million for developing a *database of homeland security-related standards* for the private sector for devices such as radiation detectors, and protocols for analysis of high explosives, chemical agents, and toxic chemicals; and

- $15 million for the *Urban Monitoring Program*, also known as *Project BioWatch*.

I list these programs in detail because they help to define the character of the newest Federal science funding agency, reporting to Charles McQueary, DHS Undersecretary for Science and Technology.

Narrowing now specifically to bioterrorism, you can see already from the budget numbers that important parts of the Nation's response to this challenge will be the responsbility of agencies other than Homeland Security. These responses are organized under three broad interagency initiatives: Project BioWatch, Project BioSense, and Project BioShield.

Project BioWatch is a cooperative effort among DHS, EPA, and the CDC's *Laboratory Response Network* to provide an early warning system for bio-threats. There are currently over 4000 atmospheric monitoring stations nation-wide for the detection of atmospheric pollutants. Under the auspices of Project BioWatch, atmospheric samples in numerous cities are monitored around-the-clock for select agents. Filters from the sampling apparatus are analyzed by the CDC network for numerous biological threat agents. If any such agents were to be detected, mechanisms and protocols are in place for DHS, CDC, and EPA to reach crucial public health decisions rapidly, and promulgate a uniform course of action for local public health officials on the "front lines." This network was established very rapidly, and much work remains to take full advantage of it, but it is functioning today.

Project BioSense is still in its infancy. It is intended to reduce the lag time between the detection of a possible bio-agent and an appropriate response. Distinct from Project BioWatch, but integrated in function, Project BioSense relies upon multiple streams of information to facilitate rapid decision-making. Monitored parameters will include environmental data from Project BioWatch, epidemiological information from hospitals administered by the Department of Defense and the Veteran's Administration, reports from pharmacies across the nation, and other sources of relevant syndromic and non-traditional data. All this information will converge at CDC's *Biointelligence Center*, first for analysis, and then, if warranted, for coordinated response. Having this single center examine data from many different sources permits the detection of patterns and anomalies that may not be apparent through other means. Moreover, the CDC has long been entrusted with both gathering

information from and disseminating information to front-line health-care providers. This new role is a logical extension of that mission, in which the CDC will work hand-in-glove with clinicians at the local level to determine if an emergency response is warranted, and the necessary magnitude of that action. I might add that CDC's exemplary response to the recent SARS epidemic demonstrated its strength in precisely this role.

Project BioShield was unveiled by President Bush in his State of the Union address in January. With the signing of the Homeland Security Appropriations Act of October 1, 2003, the President granted a total of $5.6 billion to fund this project through FY 2013, with $890 million appropriated for Fiscal Year 2004. This program has three primary provisions: *First*, Project Bioshield will spur the development and procurement of "next generation" medical countermeasures—including vaccines, drugs, and diagnostics—against biological, chemical, radiological, or nuclear agents through special contract authority. *Second*, the Act authorizes the National Institutes of Health through the National Institute of Allergy and Infectious Diseases to facilitate promising areas of research in medical countermeasures to these agents. *Third*, it establishes a new emergency use authorization for certain medical therapeutics not yet otherwise approved.

To encourage the development of countermeasures that might not otherwise be commercially viable, *Project BioShield* guarantees a market for any viable countermeasure developed in the public and private sector. It does so by purchasing these countermeasures for the Strategic National Stockpile. In order to increase national preparedness, the Department of Health and Human Services, and the Department of Homeland Security, are authorized to purchase drugs, vaccines, biological products, medical devices and other supplies in such number and amounts as may be necessary to ensure national preparedness. With the approval of the President, the Secretaries of the two Departments can purchase countermeasures up to five years before the product would normally be expected to come to market. This action would require that the Secretary of HHS determine that the product in question is eligible for procurement under BioShield, that Congress would be notified of the purchase after Presidential approval, and that payment would be made only following "substantial delivery." Project BioShield also incorporates a number of provisions that will accelerate the development cycle for innovations that show promise in combating bio-agents. If you are interested in performing research or services, or providing countermeasures under the BioShield provisions of the Homeland Security Act, I strongly encourage you to study the Act itself. It has other provisions that make it possible to respond quickly to the challenge of bioterrorism.

Interagency coordination of some actions under these three programs will be governed by explicit Memoranda of Understanding. In general, however, the normal coordination function of my office applies to science and technology for homeland security as for other Executive Branch functions. Under the National Science and Technology Council's Committee on Homeland and National Security, we have formed a Weapons of Mass Destruction Medical Countermeasures Subcommittee in partnership with DHS, DOD, and HHS. This 12-agency subcommittee works with the relevant agencies to understand and fill gaps in medical preparedness for biological, chemical, radiological and nuclear threat agents. The group collaborates on vulnerability and gap analyses, and works to define countermeasures to eradicate those gaps. Through the interagency process we continue to establish the

requirements and acquisition plans to strengthen national stockpiles of antibiotics, antitoxins, and vaccines. It is through such committees that OSTP is able to articulate research needs to the scientific community, and shape R&D agendas and budgets for the future.

All these initiatives might be described as *preparedness programs.* There is also a need for what I would call *prevention programs.* On June 12 last year, in particular, President Bush signed the *Public Health Security and Bioterrorism Preparedness and Response Act*. This law aims to increase security in facilities that hold significant biological agents that are defined on two lists: the *select agent* list that I mentioned earlier, and the *high consequence pathogen* list maintained by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). While CDC focuses on human pathogens and USDA on agricultural pathogens affecting plants and animals, a significant number of agents infect both animals and humans and are referred to as *overlap agents* in the legislation.

The new law *requires registration* with CDC or USDA for facilities that possess these select agents. That includes research laboratories, both academic and commercial; clinical diagnostic laboratories (if they keep specimens longer than needed to make the diagnosis -- 30 days extendable to 60 days); hospitals; and teaching facilities (if samples are kept in a viable form).

In addition to registration, the law *requires that facilities provide physical security measures* based on a site-specific threat assessment and risk analysis that takes into account the nature of the biological agents and their containment requirements, the need for access and type of research in which they will be employed, the actual physical plant and its location, and other environmental considerations. Individuals who are deemed to have a legitimate need for access to select agents will need to undergo a "security risk assessment," which is a database background check conducted under the aegis of the Attorney General.

To the consternation of many, the law imposes very tight deadlines on agencies and facilities to meet these requirements, but it also allows for timeframes that "minimize disruption of research or educational projects that involve biological agents and toxins and that were underway when the rule went into effect." OSTP is concerned about regulatory or bureaucratic or other barriers to research into the development of bioterrorism counter-measures and I would appreciate hearing concrete examples of such barriers.

The select agent law is an example of how preventing terrorism entails restrictions or constraints on activities that society would not choose to regulate in an ideal world. Society's demand for protection from evildoers comes into conflict with society's demand for the freedom to pursue its diverse aims without government interference. Scientific research being one of those aims, my office has a great interest in achieving a balance between these potentially antagonistic objectives. As I remarked earlier this year at a workshop on this topic organized by the Center for Strategic and International Studies and the National Academies, "[f]or a nation that would lead in science, national security includes securing the freedom to engage in open scientific discourse."

This idea did not originate with me, or with this Administration. Its current incarnation in U.S. Government policy extends back to the Reagan era National Security Decision Directive 189 (1985). That directive states that "to the maximum extent possible, the products of fundamental research [are to] remain unrestricted" and "where the national security requires control, the mechanism for control of information generated during federally funded research ... is classification." Further, "[n]o restrictions may be placed upon the conduct or reporting of federally funded fundamental research that has not received national security classification, except as provided in U.S. Statutes." "Fundamental research" was defined as that "basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community," in contrast to research for which dissemination was to be restricted due to "proprietary or national security reasons." This policy was reinforced within the present administration by National Security Adviser Condoleeza Rice in November 2001, who stated "the policy ... set forth in NSDD 189 shall remain in effect, and we will ensure that the policy is followed."

At the same time, however, technical information that might be exploited by terrorists cannot responsibly be permitted to flow without any scrutiny whatever. The same society that supports our research also wishes to be protected from its undesirable consequences. As the presidents of both the U.S. National Academy of Sciences and the United Kingdom Royal Society said in a joint statement on November 8, 2002 "researchers in the biological sciences again need to take responsibility for helping to prevent the potential misuses of their work, while being careful to preserve the vitality of their disciplines as required to contribute to human welfare."

To explore the implications of this responsibility, the National Academies convened an expert panel chaired by MIT's Gerald Fink—*the Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology*. This committee met frequently between April 2002 and January 2003 and recently released their report entitled "*Biotechnology Research in an Age of Terrorism*." I want to say a few words about this report because it falls into the category of "preventive programs," and because it calls for actions by the U.S. Government.

The Committee's goal was to "raise a culture of responsibility." Its charge was

1. "To evaluate the [current] rules, regulations, and processes ... that provide oversight of research on pathogens and other potentially hazardous biotechnologies ... ;

2. To determine whether [these] rules, regulations, [etc.] ... are sufficient to prevent the misdirected application of the aforementioned scientific inquiry;

3. To recommend improvements to prevent the destructive application of biotechnological innovation, while continuing to foster an environment conducive to legitimate research."

The committee's recommendations for achieving these goals included educating the scientific community, reviewing plans for certain experiments, reviewing research results at the publication stage, creating a "*National Security Advisory Board for Biodefense*," and controlling certain sensitive

materials. I will do my part "to educate the community" by repeating some of the recommendations here in more detail:

The Committee thought scientists should be more aware of the "dual use" dilemma, and work through a series of structured meetings and symposia to define and promulgate what scientists should do to avoid inadvertently advancing the causes of biowarfare and bioterrorism.

The Committee recommended that the Department of Health and Human Services establish a review system for experimental plans, similar to the existing NIH system for reviewing recombinant DNA proposals. What proposals would merit a review? The list is a major product of the committee: A review would trigger on experiments that would potentially:

1. Render a vaccine to a pathogen ineffective;

2. Confer antibiotic resistance to a pathogen so as to decrease the effectiveness of a countermeasure—for example, by increasing the resistance of Yersinia pestis, the organism responsible for plague, to standard therapeutics;

3. Increase the virulence of a pathogen, or make a formerly non-virulent entity virulent, such as by introducing a cereolysin toxin gene into the genome of Bacillus anthracis;

4. Increase the transmissibility of a pathogen, for example by making a pathogen not normally transmissible by the aerosolized sputum of a cough transmissible by such;

5. Increase the host range of a pathogen;

6. Enable evasion of diagnostic or detection modalities. Micro-encapsulation or altering DNA sequences so as to change the antigenic characteristics of the pathogen is one such example; or

7. Ease or enable the weaponization of a pathogen—for example making it highly resistant to dehydration.

The Committee suggested that Institutional Biosafety Committees (IBC's) should be the first level of review for experiments of concern. These committees are already in place at over 400 institutions in the United States, as they are mandatory at any institution receiving NIH funding for research with recombinant DNA, and have been adopted voluntarily by a large number of facilities.

Experiments determined by the IBC to be questionable could be referred in turn to another body already in place—the Recombinant DNA Advisory Committee, or "RAC," which has a proven track record for making prudent and reasoned recommendations about what kind of work should be allowed to move forward, and what should not. The final level of authority, as for experiments with recombinant DNA, would be the NIH Director.

The Fink Committee recognized that publication of research results, once the research is approved through the above process, might still result in dissemination of information that could be used with ill-intent. Given the profound "dual-use" nature of much medical knowledge, further effective regulation of publication would have to be carried out very carefully to avoid "throwing the baby out with the bath water." The Committee thought this is an area best suited for self-governance by the scientific community. A promising start consistent with this recommendation is the statement by the publishers of a prominent group of scientific journals shortly after the CSIS/NAS meeting earlier this year, acknowledging the need for a special system of review of submitted papers that may have bioterrorism implications. The areas of concern identified by the Fink Committee should help such a review.

The Fink Committee calls for the creation of a National Science Advisory Board for Biodefense within the Department of Health and Human Services that would be part of an effort to provide the required advice, guidance, and leadership for implementing the recommended changes. I do not know at this time whether HHS will act on this recommendation, but the functions described for the proposed Board are important, and ought to be performed by some organization with official status.

Finally, the Committee found that current statutes, including the Bioterrorism Preparedness and Response Act of 2002 and the listing of select biological threat agents, have been highly effective in controlling sensitive materials. They concluded that these statutes adequately allow for the fact that too severe a level of constraint would unduly impede legitimate research, while leaving issues of endemic pathogens and agents available in the international arena unaddressed.

Concrete steps are already being taken to implement some of the recommendations in this report. Both OSTP and the Homeland Security Council have been in close consultation with Secretary Thompson at the Department of Health and Human Services to form a strategy of implementation. In addition, OSTP and the Homeland Security Council have convened an inter-agency team to review the recommendations of the NRC panel to create a National Security Advisory Board for Biodefense and to propose a mechanism by which the Federal government might implement such an advisory board.

During the past two years, Executive Branch offices and agencies have enjoyed a remarkable and productive relationship with the scientific community. From the difficult moments immediately following the terrorist attacks, the anxiety of the anthrax incidents, and extending throughout the sequence of proposals and actions that have taken us as a nation into a new era of awareness and concern about homeland security, federal officials and scientists from all sectors of society have worked closely together. The relationship is not always easy, but it is necessary. I am grateful to you and your colleagues for engaging these difficult issues in a spirit that appropriately superposes cooperation with concern. Continued progress toward security with freedom will require that this relationship be strengthened and extended into the future.

Thank you.