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Good Morning, Mr., Chairman and members of the Committee. I am Dr. Richard Klausner, Senior Fellow at the National Academy of Sciences and Special Advisor to the Presidents for Counterterrorism. I am also Chair of the National Academies' Committee for Science and Technology (S&T) Agenda for Countering Terrorism. The Academies include the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The National Academy of Sciences was chartered by Congress in 1863 to advise the government on matters of science and technology. The National Research Council (NRC), the operating arm of the Academies, was established in 1916. The National Academy of Engineering was established in 1964. The Institute of Medicine was established in 1970. These institutions provide independent advice on science and technology and related policies for the federal government, including executive and legislative branches.

The National Academies began mobilizing the S&T community to address the threats presented by terrorism immediately after the horrific events of September 11th. It assembled a distinguished group of scientists, engineers, health care professionals, industrialists and former high level government officials on September 26th to develop a series of initiatives which the Presidents, themselves, could immediately initiate from their own resources while government was mobilizing its own activity. Among the suggestions emerging from that meeting which have all now been initiated, were the following:

1. the development of an S&T agenda for addressing the comprehensive range of vulnerabilities our country faces extending over the next decade and how S&T can best respond to them; this work is being undertaken by a distinguished, eclectic committee which I co-chair with Professor Lewis Branscomb of the Kennedy School at Harvard. This work is being closely coordinated with the Office of Science and Technology Policy (OSTP) and, through that office, with the Office of Home Land Security. I shall provide some details of the committee's work subsequently;

2. near-term technical assistance to the government through real time advice by scientific experts on topics panels chosen by the inter-agency Technical Support Working Group (TSWG) and, separately, by the U.S. Postal Service.

3. an intensification of international activities on both a bilateral and multi-lateral basis through a variety of institutional mechanisms. These include discussions with scientists in key countries on how to lessen the risk of proliferation of weapons of mass destruction under the auspices of the NAS Committee on International Safeguards and Arms Control. They also include multi-lateral academy-academy discussions under the Inter Academy Panel and Council and

bilateral activities of a wide variety of sorts, including discussions with national academies in Moslem countries.

5. Technical and policy work on bioterrorism under the broader, on-going activity on infectious diseases and vaccine policy, largely within the Institute of Medicine;
5. Workshop and studies on issues affecting universities arising out of Terrorism Events. Issues include student visa and tracking policies and systems and the management of biological research security in university laboratories.

In addition to the kinds of specific initiatives enumerated above, there have been a number of counter-terrorism activities related underway under the auspices of the more than 80 standing boards throughout the National Research Council. Some of these are activities and and studies were begun considerably before September 11th, but they are even more timely because of the events of that day.[1] Others have been initiated since September 11th in response to agency requests.

I have attached a document, entitled *"Summary of Selected Counter-Terrorism Initiatives by the National Academies,"* dated December 18, 2001, which summarizes the comprehensive scope of activities which have been initiated either by the Academy Presidents or by standing committees throughout the National Academies complex.

I wish to offer several perspectives on the role of science and technology as related to bio-terrorism, as an example of broader application, in the time remaining.

It is clear to me that we cannot solve the comprehensive and daunting threat presented by bio-terrorism without the active and sustained effort of the science and technology community. Indeed, the S&T community is ready and willing to respond. But how do we connect all the relevant S&T communities with the many requirements bio-terrorism presents at both the national and local level?

One part of the approach is embodied in the comprehensive, S&T visioning project for combating terrorism I am co-chairing. This project is aimed at helping the Federal Government, and more specifically, the Executive Office of the President, to use effectively the nation's and the world's scientific and technical community in a timely response to the threat of catastrophic terrorism. Under the sponsorship of the National Academies , a distinguished assembly of scientists and engineers will help the government develop a vision for how S&T can address the complex challenges presented by terrorism.

The project will undertake the following tasks to be presented in a report in six months: (1)

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[1] Examples include the work by the IOM on anthrax vaccine policy for the military and the development of tools for evaluating the metropolitan medicine response system program. (See, Phase 1 Report, Frederick Manning, Lewis Goldfranks, Eds, Strategic Mechanisms for Improving OEP Analysis of Preparations for biological, Chemical, Radiological Terrorism, Washington, D.C.: National Academy Press, October 10, 2001.)

prepare a carefully delineated framework for the application of science and technology for countering terrorism, (2) develop a comprehensive threat-based agenda by which S&T can address challenges presented by terrorism to our security; (3) characterize cross-cutting issues, and (4) address implementation hurdles with recommendations for overcoming them.

The S&T vision and agenda will be developed in the following areas:

- Biological
- Chemical
- Nuclear and Radiological
- Information technology
- Transportation
- Energy facilities, cities and fixed infrastructure
- Behavioral, social and institutional issues
- Systems cross-cutting issues

We believe the work of this committee will provide the an integrated science and technology vision and program plan, extending over a decade, for combating terrorism. We know of no similar activity underway anywhere else. We believe it will be quite useful in helping the executive and legislative branches in allocating resources against the comprehensive threats presented by terrorism.. After completion of our report in May, I would be happy to return to present the report's key findings and recommendations.

Parallel activities are underway to help connect the relevant S&T community with immediate technical requirements of federal and local agencies. One is a project in which the Academies are inviting scientific experts to meet with government representatives in one-day meetings to address how better to address near term requirements of federal and local agencies. Although no written reports are produced and no formal Academy advice is provided, the dialogue is beneficial to federal agencies, including the 80 member, inter-agency Technical Support Working Group (TSWG) on counter-terrorism. In December, we invited scientific experts to engage in dialogue with TSWG panels on bio/chemical forensics and bio/chemical decontamination. Another meeting is planned next month on through-structure imaging. Earlier, we met with U.S. Postal Service personnel to assist the service in evaluating radiation technologies to sanitize contaminated mail.

Within the Institute of Medicine (IOM), a number of public health strategies to address t terrorist threats have been undertaken. The goal of this activity is to provide guidance on specific issues of national, local and individual concern, within the framework of a comprehensive strategy to assure the health of the public in the 21st century. Projects include a comprehensive bioterrorism threat assessment. This assessment was initiated within the Forum on Emerging Infections. A November workshop, addressed "Biological Threats and Terrorism: How Prepared Are We?"

Other components of the IOM Strategy include communications, legal authorities, and vaccine policy components. The adequacy of surveillance systems and laboratory capacity are being addressed as well as the psychological consequences of terrorism and the long-term mental health consequences of asymmetric warfare. The IOM has already commenced the evaluation of the adequacy of local public health agencies and organizations to address the new bioterrorism threats with which they are confronted on top of the general spectrum of naturally occurring infectious diseases.

Many agencies throughout the government work with scientists within their respective domains. But the task for the Office of Home Land Security is to cut across all these domains and mobilize scientists for the new challenges presented by terrorism and to connect scientists working in relevant disciplines with the requirements presented by counter-terrorism over the long term.

We currently do not have adequate processes and structures in place to carry out the necessary connectivity not only among agencies but among the participants in the S&T enterprise: sponsoring agencies, users (both federal and local), and the diffuse research community that must be mobilized to address terrorism.

There are three over-arching issues relating to bioterrorism that I believe require focused attention.

The first issue is to determine the ingredients necessary to mobilize all the relevant S&T communities to address the range of threats presented by bioterrorism. These threats include both the potential bio-terrorist weapons which exist today, e.g. smallpox, anthrax, botulism, as well as genetically modified organisms that can be made toxic and used as weapons. To engage the S&T communities fully will require effective communication of government needs and priorities as well as a sustained financial commitment by government to address these priorities.

The second issue is how do we solve specific bio-challenges, solutions to which may span the "silos" of existing disciplines, agencies and sectors. We must develop the necessary linkages between S&T, the private sector (a necessary partner for technology development), and the government, which is the most significant sources of resources for scientific research and development. We need to find ways to make the necessary linkages across the "silos" that exist presently in agencies, disciplines and sectors. Are the agencies funded in such a way today that they have sufficient *incentives* to ensure that they do come together for the purposes we now must urgently address across many agencies? Do government agencies have the tools to encourage participation of and partnering with the private sector? Can agencies mobilize communication and management strategies that will engage creative solutions from needed disciplines or across existing disciplines?

The third issue we must address is how the public and private sectors may more effectively partner to address bio threats at all stages of development: from research, through

development, final product introduction and market penetration and wide use. The "products"are varied. They include drugs, vaccines, detectors and other items across the complete spectrum of prevention, detection, response, recovery and attribution. We realize that we need very large dose numbers of vaccines, anti-bacterials, anti-virals and mocrobial agents to protect the public and limit the spread of disease. Yet the "market," alone will not produce these in sufficient numbers and at the quality needed. The government will have to ensure that promising projects in priority areas can be shepherded through to a productive end point and made available for use of the appropriate federal, state, county, local and public levels. This will require a reassessment of management tools and traditions as well as new infrastructure.

As the Council of the Institute of Medicine stated in its *Statement on Vaccine Development*, dated November 5, 2001:

> The events following the tragedies of September 11,2001, have reemphasized a serious defect in America's capacity to deal with biological agents used in terrorist attacks. The capacity to develop, produce, and store vaccines to deal with these agents are inadequate to meet the nation's needs. In 1993 the Institute of Medicine published *The Children's Vaccine Initiative: Achieving the Vision*. In assessing the national and international situation, the committee said, "because the private sector alone cannot sustain the costs and risks associated with the development of most CVI vaccines, and because the successful development of vaccines requires an integrated process, the committee recommends that an entity, tentatively called the National Vaccine Authority (NVA), be organized to advance the development, production, and procurement of new and improved vaccines of limited commercial potential but of global public health need."[2]

In a 1992 report, *Emerging Infections: Microbial threats to Health in the United States*, another IOM committee recommended the development of an integrated management structure within the federal government for acquiring vaccines, as well as a facility for developing and producing vaccines with government support.[3]

Evidence for the inability of the private sector to meet the country's needs for vaccines has accumulated substantially since the 1993 report. Fewer private companies are manufacturing vaccines. Continually needed vaccines such as the tetanus and influenza vaccines are in increasingly short supply. The availability of influenza vaccines has been delayed over the past several years and in 2000, one company stopped production. Pneumonococcal conjugate

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[2] Mitchell, V.S., Philipose, N.M., and Sanford, J.P., eds. The Children's Vaccine Initiative: Achieving the Vision. Washington, D.C.: National Academy Press, 1993.

[3] Lederberg, J., Shope, R.E., and Oaks, S.C., Jr., eds. Emerging Infections: Microbial Threats to Health in the United States. Washington, D.C.: National Academy Press, 1992.

vaccine is unavailable in several states because of the sole source manufacturer'' inability to meet demands. Only one source is currently available for meningococcal varicella and measles-mumps-rubella vaccines.

> There are just four major vaccine manufacturers in the world today, and only two in the United States.[4] There were four times that number only 20 years ago. There are many small new research and development companies backed by venture capital and devoted to vaccine development. Many are working on anticancer vaccines for which market forces may be enough to keep them in production. However, good products developed by these startups to combat infectious diseases often do not come to market because of the very large costs of testing in pilot studies and in manufacturing.
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> Prior to the events of September 11, the delays and problems faced by both the Department of Health and Human Services and Department of Defense in developing and procuring a cell-culture smallpox vaccine provide convincing evidence that major changes are needed at the national level. With the government guaranteeing payment in this time of national need, several potential manufacturers have come forward. This is an ad hoc example of a larger national need for mechanisms to obtain other public-good vaccines on an ongoing basis, and not just under extenuating circumstances when there is a great deal of public awareness of the need for vaccines.
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> … The Children's Vaccine Initiative committee listed the functions of a National Vaccine Authority. … They now have a broader importance to America, as the potential need for vaccines required to meet biological threats increases. The IOM Council believes the Authority should focus its attention upon vaccines that will not be adequately produced by existing public or private entities.
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> Recently, proposals have been made for the creation of a government-owned, contractor-operated national vaccine facility. The IOM Council believes this is one in a spectrum of public-private ventures by which a NVA could facilitate development and production of needed vaccines. … While a major priority for this facility would be to develop vaccines necessary to protect American troops and for use against bioterrorism, the facility also should be charged with production of other vaccines that are in scarce supply and would not otherwise be provided in the public or private sectors. In some cases in which there are few private sector uses, the facility would become the principal source of such vaccines. In other cases, as variety of public and private partnerships could be undertaken to produce needed vaccines.[5]

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[4] Merck Vaccine Division (parent company is Merck Pharmaceuticals) and Wyeth-Lederle Vaccines (parent company is American Home Products Corporation) are U.S.-based companies. Aventis Pasteur and GlaxoSmithKline operate within the United States and have products licensed by the FDA for use in the United States, but they are companies based in other countries.

[5] Pearson, G.W. The Children's Vaccine Initiative: Continuing Activities. Washington, D.C.: National Academy Press, 1995.

> The Council of the IOM believes that the development of a National Vaccine Authority is long overdue. It could be created within the Department of Health and Human Services, in collaboration with the Department of Defense or as a joint effort of the two departments. Moreover, the Council believes that establishment of a government-owned, contractor-operated facility for research, development, and production of vaccines is essential to meeting the country's public health needs, particularly those related to bioterrorism and protection of our armed forces…[6]

I believe there are three actions that should be initiated with the encouragement of Congress:

First, the National Institutes of Health (NIH) needs to consider whether it needs to establish an Advanced Research Projects Agency – perhaps modeled on the DARPA model – to more effectively engage and harness critical creativity and better link it to both local and federal requirements and accelerate the rate of introduction of new technology into broad use.

Secondly, the government should implement The Institute of Medicine recommendation to establish a National Vaccine Authority (NVA), charged with carrying out the functions spelled out in the November 5 IOM Statement.

Thirdly, serious consideration should be given to the establishment of new funding and management tools that encourage and sustain public-private partnership. Lessons should be captured from successful existing examples such as the efforts undertaken by NIAID and expanded upon to meet current needs.

We clearly need a better national approach for anti-toxin, anti-microbial drugs development, production and storage. We are on the cusp of an explosion in genome development. In addition to the benefits of such an evolution are great risks: there will be the potential for many more drug "weapons." Markets, alone, will not drive this development and production activity, yet partnership with the private sector is essential for realizing the goal.

Underlying the effectiveness of all of the recommendations is the need for complete and effective communication and information exchange. This applies across federal, state and local agencies; among the government, academia and industry; and across the silos of scientific, engineering, and health care disciplines. Critical to this effort is the need to develop ways to better access information and affect more rapid response capability for use at both the national and local levels. Part of this challenge is related to improved information management systems; another is to assuring the existence of accurate and authoritative information sources; yet another to addressing the need for better training, and better real-time linkages among those public and private-sector institutions which share responsibilities and capabilities to protect (and improve)

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[6] The Complete *Statement* is attached to this testimony. It includes the listing of specific functions appropriate for the NVA.

the health of the public in the 21st century.

I have appreciated the opportunity to testify before the Senate Committee on Commerce, Science, and Transportation today on the important issues you have raised relating to Home Land Security against bioterrorism.

I would be pleased now to answer any questions you may have and request my complete statement and attachment be included in the record.