Full Committee Hearing Notice - Federal Biodefense Readiness
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Witness:
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Testimony:
Mr. Chairman and Members of the Committee, thank you for inviting me to discuss how the National Institutes of Health (NIH) is helping to increase national preparedness against terrorist threats. The events of September 11, 2001, and the anthrax attacks that followed changed forever our collective thinking about the Nation's vulnerability to terrorist attacks. In response, the NIH and our sister agencies in the Department of Health and Human Services (DHHS), the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), have strengthened and expanded programs that will markedly enhance our ability to protect the American people against a broad range of potentially deadly terrorist threats. Indeed, many of these efforts have already borne fruit, and bioterrorism readiness stands at an all-time high. Nonetheless, we have more to do to develop the full complement of medical countermeasures and procedures that homeland security requires.

Today, I will address how the NIH is contributing to the nation's capacity to counter bioterrorist threats. In Fiscal Years 2002 and 2003, the NIH greatly accelerated and expanded its research program on dangerous microbes and their toxins, an emphasis that reflects the lead role of the NIH, and particularly the National Institute of Allergy and Infectious Diseases (NIAID), in federally supported research on human infectious diseases. For Fiscal Year 2003, the NIH received a budget appropriation of over $1.5 billion for biodefense research, an unprecedented amount for any single program in the history of NIH.

More recently, the NIH has begun to identify next steps to implements its responsibility to develop a research agenda to address chemical and nuclear/radiological threats, as well as interventions to address the mental health impact of terrorism on individuals and society. The ultimate goal of these efforts is to develop an armamentarium of vaccines, therapeutics, and diagnostics that can protect the people of the United States against dangerous pathogens, toxins, chemicals, and radiological agents. Our bioterrorism-related research and development efforts are closely intertwined with the activities of the CDC, the FDA, and the Department of Defense (DoD).

The success of our efforts to develop safe and effective biomedical countermeasures against terrorist threats depends on a balance of basic and product-driven research, sufficient infrastructure and resources, and the outstanding men and women whose expertise and commitment make the entire enterprise possible. With this emphasis in mind, my remarks today will focus on NIH's efforts to: (1) develop a broad range of medical countermeasures, including vaccines, against terrorist threats and emerging infectious diseases; (2) develop the necessary research infrastructure, including specialized laboratory facilities and equipment; (3) enhance collaborations with other federal agencies and the private sector; and (4) develop and sustain the human capital that is central to all our activities.

Developing Medical Countermeasures to Terrorist Agents

As the United States confronts the threat of terrorism, it is imperative that the Federal government develop the means by which to protect its citizens. The NIH response to this challenge has been unprecedented in its swiftness and scope. Aggressively managed, milestone-driven, interagency-coordinated efforts, and enhanced partnerships with industry have already resulted in important progress in basic research and in the development of biodefense countermeasures.

Last year, the NIH devised an intensive strategic planning process to shape its biodefense research program. These efforts resulted in the development of the NIAID Strategic Plan for Biodefense Research, as well as comprehensive research agendas for Category A agents, and Category B and C priority pathogens. Prepared in consultation with blue ribbon panels of experts, the research agendas delineate immediate, intermediate, and long-range plans for basic research and the development of vaccines, drugs, and diagnostics. Category A agents are considered to be the most serious bioterrorist threats. They include smallpox, anthrax, botulinum toxin, plague, tularemia, and hemorrhagic fever viruses such as Ebola. Category B and C priority pathogens include many food and waterborne microbes such as those that cause cholera, typhoid fever, encephalitis, and certain forms of dysentery. In accord with the priorities outlined in its research agendas, NIAID developed a total of 46 biodefense initiatives in Fiscal Years 2002 and 2003. The response from the scientific community was swift and strong; NIAID has seen a 30 percent increase in the number of grant applications, the vast majority of which are for biodefense.

NIH has already advanced the development of vaccines and therapies for smallpox and anthrax. Last year, for example, NIH-supported scientists demonstrated that the existing U.S. supply of smallpox vaccine was still potent and could be diluted five-fold and retain the ability to stimulate the skin lesion “take” considered an indication of the vaccine’s effectiveness. The discovery made it possible to greatly expand the number of doses of smallpox vaccine in the United States. NIH is now developing and testing next-generation, attenuated smallpox vaccines such as modified vaccinia Ankara (MVA) that can be used safely in people whose immune systems are compromised, in pregnant women, in people with skin conditions such as eczema and atopic dermatitis, and in other vulnerable populations for whom the existing vaccine is not recommended. NIH is also testing antiviral compounds as potential therapies for smallpox, developing antibodies that could be used to treat complications caused by the current smallpox vaccine, and sequencing the genomes of smallpox and related poxviruses to identify potential molecular targets for new drug and vaccine development.

Progress on anthrax is following a similar pattern of success. Last year, NIH-funded scientists identified the site on a human cell that binds the anthrax toxin and developed a compound that may block its lethal effects. The information gained through these and other studies will likely hasten the development of new drugs to treat anthrax. In May 2003, NIH-supported investigators at The Institute of Genomic Research in Rockville, MD, determined the complete genetic sequence of the strain of the anthrax microbe used in the 2001 mail attacks. In addition to providing valuable forensic information, this achievement may give scientists valuable clues about designing drugs and vaccines that capitalize on the bacterium’s vulnerabilities. And as of July 2003, four clinical trials of a next-generation, DNA-based vaccine for anthrax called recombinant Protective Antigen (rPA) are underway.

Future NIH biodefense research will reveal more about the basic biology of these and other microbes, identify the mechanisms by which they cause disease, identify factors in the human innate and adaptive immune response to these microbes, and develop new and improved interventions that can prevent and treat diseases caused by Category A, B, and C agents. For example, NIH is developing and testing candidate vaccines for Ebola and is currently in the planning stages for initiation of a Phase I clinical trial to evaluate a candidate DNA vaccine for Ebola. Over a dozen more research initiatives are planned for Fiscal Year 2004, all of which will help accelerate the development of medical countermeasures against biological agents that could be used as weapons of terrorism.
Over the past several months, NIH has also begun to examine several other areas of concern: nuclear/radiological terrorism, chemical terrorism, and the psychosocial impact of traumatic events. Earlier this year, we convened panels of experts in radiobiology and medical chemical defense to identify research opportunities in medical countermeasures. On February 26, 2003, NIH convened a meeting that included scientists of the NIAID, National Cancer Institute (NCI), the Armed Forces Radiobiology Research Institute, the National Academy of Sciences (NAS), other government agencies, and academia, to identify priorities in the development of medical countermeasures against nuclear/radiological terrorism. This meeting was a logical sequel to two NCI-sponsored workshops held in 2000 and 2002 that reviewed information on tissue damage from ionizing radiation and possible mechanisms of protection. On March 19, we convened a panel of experts that included representatives of the NAS, academia, industry, other federal agencies, including the DoD and the Army Medical Research Institute of Chemical Defense, the newly created Department of Homeland Security, and NIH Institutes and Centers. The panel was charged to identify gaps in scientific knowledge about chemical injury and repair, and to identify priorities for the research and development of medical countermeasures. These meetings have provided an excellent framework for new medical product development and greater homeland security.
The National Institute of Mental Health (NIMH) has a program committed to research on mass casualties and trauma. Within several months of the attacks on the World Trade Center and Pentagon and the anthrax mailings, the NIMH expedited the award of grants to assess the mental health impact of these terrorist actions. The institute also convened, with other agencies, a major national workshop on mental health needs in disaster response. The NIMH is exploring additional behavioral/mental health research aimed at two problems, the treatment of trauma in individuals, and communication with the public during disasters and other traumatic events.

Developing the Research Infrastructure

Continuing progress in our efforts to develop medical countermeasures against a broad range of terrorist agents also depends on the availability of specialized resources that enhance the NIH research infrastructure. Key among these resources is a nationwide network of Regional Centers of Excellence for Biodefense and Emerging Infectious Disease Research and the construction of the Regional and National Biocontainment Laboratories, all of which are being launched in Fiscal Year 2003. These facilities will serve as national resources for biodefense research and product development, as well as for the study of other infectious diseases such as SARS and the West Nile virus, which require specialized biocontainment laboratories for research. The new centers and laboratories will include a small number of Biosafety Level (BSL)-3 and BSL-4

laboratories, which have the containment safeguards necessary to study highly pathogenic organisms. Only four BSL-4 laboratories exist in the United States today, which limits the ability to conduct safe and efficient biodefense research; the new facilities will substantially increase our country's biodefense research capacity. Review of applications for the Regional Centers of Excellence and the Regional and National Biocontainment Laboratories programs is occurring now, and awards will be made this fall. In addition to these extramural facilities, NIH is planning the construction of new intramural facilities, which will include BSL-3 and 4 laboratories at Fort Detrick and Rocky Mountain Laboratories, and BSL-3 laboratories at the NIH campus in Bethesda. NIH is also investing in other research resources necessary for meeting our biodefense goals. These include expanding our capacity for large-scale genome sequencing, developing new technologies to mine the wealth of data generated from genomic research, and establishing a national biodefense research reagent repository.

Enhancing Collaborations

Collaborations with other federal agencies, private industry, and academia have always been a cornerstone of NIH's programs of research and development to promote public health. For the past two years, we have expanded these collaborations in many directions to bring together the multidisciplinary expertise and make possible the rapid response required to address terrorist threats. These partnerships have contributed greatly to the progress in the biodefense enterprise to which I have already alluded. For example, our ability to initiate clinical trials to test the next-generation rPA vaccine for anthrax resulted largely from collaboration between NIH and DoD. NIH has also developed an interagency agreement with the U.S. Army Medical Research Institute of Infectious Diseases that allows for cross-utilization of resources and joint research projects of high national importance, such as next-generation vaccines against smallpox. NIH is also working closely with the FDA and DoD in the evaluation of antimicrobial drugs against high-threat agents such as plague and tularemia.

Also critical to our continued success are partnerships with private industry. Unfortunately, many biodefense products provide insufficient incentive for private-sector engagement because there may be no viable commercial market. Within the limits of current statutory authority, NIH continues to develop new and innovative approaches to public-private partnerships to overcome such obstacles. The Project BioShield legislation now under consideration would provide significant funding for countermeasures against the highest priority threat agents. It would also greatly strengthen our ability to respond to the many challenges associated with biodefense research and development by providing streamlined authority, increased flexibility in awarding grants and cooperative agreements, expedited peer review procedures, bolstered authority for acquisition, construction, and renovation of facilities, and greater flexibility in hiring technical experts.

Our plan is to work closely with colleagues elsewhere in government, including the Departments of Homeland Security, Defense, and Energy and the NAS to ensure that our efforts to develop chemical, biological, radiological, and nuclear countermeasures are successful.

Developing and Sustaining Human Capital

A fundamental element in our ability to protect the American people against terrorist threats is personnel. We must hire, train, and retain the most highly qualified and

dedicated men and women to form the core of the NIH research enterprise. Our current personnel levels have been sufficient to foster the progress in biodefense research that I have described.

NIH is committed to the education and training of biomedical research scientists to meet future challenges. Recently, NIH initiated a number of programs to provide research training and career development opportunities in the area of biodefense. These opportunities, in the form of institutional training grants, individual pre- and postdoctoral fellowships, and career development awards in both basic and clinical research, will ensure a continuum of highly qualified men and women in this crucial area of research. We believe that the talent exists to conduct the necessary research. Our challenge across the federal government is to find more effective ways to attract, hire, nurture, and retain qualified, committed people into national service.

Conclusion

Today, the United States faces a challenge that demands a rapid and coordinated scientific response. This challenge appears new and sinister because it arises from the deliberate use of deadly microbes, toxins, chemicals, and ionizing radiation as weapons against citizens. However, the tools and processes we need to combat these forms of terrorism are familiar to us. They include fundamental research to discover the mechanisms of injury and disease, investigations that lead us to a better understanding of how humans respond to these potential weapons, and the translation of that fundamental knowledge into safe and effective countermeasures. Indeed, the experience and expertise of the NIH places us in a unique position to accelerate the development of countermeasures needed by Americans and people around the world to protect them against the threat of terrorism in the 21st century.

Mr. Chairman, this concludes my statement. I will be happy to answer any questions you and the other Members of the Committee might have.