Center for the Study of the Presidency

Marshalling Science, Bridging the Gap: How to Win the War Against Terrorism and Build a Better Peace

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How to Win the War Against Terrorism and Build a Better Peace

Senator William Frist, M.D.

Dr. John H. Marburger III

Dr. Joshua Lederberg

Dr. William Schneider, Jr.

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Center for the Study of the Presidency
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About the Center for the Study of the Presidency

The Center for the Study of the Presidency, founded in 1965, is a non-profit, non-partisan 501(c)(3) organization dedicated to serving as a central resource on issues affecting the modern Presidency. As the foremost organization in the United States dedicated to this effort, the Center endeavors to study all aspects of the American Presidency, to strengthen the Executive-Legislative Branch relationship, and to encourage public service, especially among young Americans.

About this Project

Several years ago, in effort to strengthen the Presidency, the Center convened S&T policy experts and former government officials and produced *Advancing Innovation: Improving the S&T Advisory Structure and Policy Process* (Washington, D.C., Winter 2000). The current project, supported in part by the Richard Lounsbery Foundation and the Alfred P. Sloan Foundation, identifies long range basic research vulnerabilities and opportunities and calls for greater use of national S&T resources in the war on terrorism.

Other CSP publications include:

Presidential Studies Quarterly (ISSN 0360-4918)

Lessons for the 21st Century: Vulnerability and Surprise, December 7, 1941 and September 11, 2001 (Washington, D.C., March 2002)

Panel Report to the President and Congress on Comprehensive Strategic Reform (Washington, D.C., September 2001)

Triumphs and Tragedies of the Modern Presidency: Seventy-Six Case Studies in Presidential Leadership, Praeger Publishers, Westport, Connecticut (January 2001)

Forward Strategic Empowerment: Synergies Between CINCs, the State Department and Other Agencies (Washington, D.C., 2001)

A Call for Transformational Leadership: U.S. and Japan (Tokyo, 2001)

Dialogues on Presidential Leadership: The President, Congress and the Media (Washington, D.C., 2000)

In Harm's Way: Intervention and Prevention (Washington, D.C., 2000)

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INTRODUCTION

Anticipating U.S. involvement in World War II, President Roosevelt on June 27, 1940 created the National Defense Research Committee (NDRC) which its first director, Vannevar Bush, the farsighted president of the Carnegie Institution of Washington, turned into a new model of public/private research. NDRC's successor, the Office of Scientific Research and Development (OSRD), led the effort to develop radar, nuclear weapons, the proximity fuse and other weapons that enabled the United States not only to win that war, but the Cold War as well. We are faced with a similar challenge today, as stated in a recent Center publication on Pearl Harbor and September 11th, *Lessons for the 21st Century: Vulnerability and Surprise*. Surely, our nation must marshal its scientific and technical resources to win the war on global terrorism.

We are now engaged in a new kind of warfare. States no longer are the enemy, or at least the obvious one, and institutionalized responses such as NATO, the United Nations and economic sanctions cannot be as effective against a loose confederation of terrorists as those same tools might be against sovereign nations. Instead, intelligence, detection, integrated weapon systems—often drawn together from commonly available technologies—and the ability to quickly form and sustain alliances with people and cultures heretofore unfamiliar are the keys to success. Innovation, science and technology are key to the effective use of many of these new tools. This report identifies how the nation can better create, identify, organize and apply these new tools both to homeland security and the war on global terrorism.

Strengthening Presidential decision-making is a key goal of the Center for the Study of the Presidency. So, too, is improving Executive-Legislative relations. With both objectives in mind, the Center recently honored Senator Bill Frist, the Senate's only physician and a leading bioterrorism expert with its first Publius Award, named in honor of the authors of *The Federalist Papers*. During his acceptance remarks, Senator Frist called anthrax "more powerful than a hydrogen bomb." He also noted that the risk of bioterrorism is real and growing, and that while we no longer are unprepared, we remain under-prepared. He recommends strengthening our public health system, improving communication among first responders, and development of "dual-use" technologies, that is, ones with civilian as well as military applications. Many of the slides he used that evening are reproduced in this publication.

We are now engaged in a new kind of warfare.

The next day, the Center invited four national experts to participate in a Capitol Hill panel on bridging the gap between research and policy in the context of the September 11th tragedy. Dr. John Marburger III, the President's Science Advisor, explained how today's research efforts will differ from those undertaken during World War II when the federal government recruited a large number of scientists who turned abstract theories into radar, nuclear devices and other weapons. To meet the current challenge, Dr. Marburger recommends both a vigorous R&D program to "create and deploy anti-terrorist weapons," and "a comparable R&D initiative—to better understand how we should implement our strategic plan to fight against terrorism." Dr. William Schneider, Jr., Director of the Defense Science Board, took up this second theme and spoke forcefully about the "very practical task at hand, namely, identifying the science and technology requirements for dealing with terrorists." He warns against exporting technology that others might use against us. And he praises the military's real-time ability to turn "Radio Shack" technology into weapons tailored for a particular terrain or military objective.

Our third panelist, Dr. Joshua Lederberg, former President of Rockefeller University and a Nobel Laureate, spoke about establishing an overriding policy goal, namely "a global regime

of zero tolerance on the use of biological weapons, in any circumstance." He then drew on his extensive experience developing the background for our national plans for marshalling resources against terrorism. Dr. Lederberg argued that the United States must keep its hands clean, conduct additional research to better treat anthrax infections, improve epidemiological modeling and surveillance, establish research priorities for the development of counter-terrorism pharmaceuticals, and organize a cadre of certified physicians (with experience and judgment equal to Food and Drug Administration officials) who can "make life-saving decisions when the public's health is endangered."

Dr. Homer Neal, a Center trustee and high-energy particle physicist who heads the University of Michigan's ATLAS Project and is a former member of the U.S. National Science Board, chaired the panel. In his remarks, Dr. Neal notes that universities occupy an important role in the area of homeland defense. As he points out, universities are not only the source of the fundamental research that underlies many military technologies, but also the one institution that produces both the technical workforce needed in modern society and the individuals with "broad language skills and a deep understanding of other cultures." Moreover, he notes the strong link between research universities, the national laboratories and private industry "provides a powerful mechanism for technology transfer."

Our global policy goal should be zero tolerance on the use of biological weapons, in any circumstance.

Marshalling Science, Bridging the Gap: How to Win the War Against Terrorism and Build a Better Peace carries forward the Center's work on *Advancing Innovation: Improving the S&T Advisory Structure and Policy Process* by identifying the challenge before us, defining the terms of engagement and mapping out the organizational structures and intellectual tools needed to prevail in the global war against terrorism. The many insights contained in these pages could not be more timely or on target. As we go to press, the President has proposed a new Department of Homeland Security that will oversee many of the research agenda, security issues, and resources discussed here. Moreover, the National Research Council is about to release its report on using science and technology to counter terrorism. We hope that our own slim volume contributes to the formation of an effective new Cabinet office and to countering terrorism, and that, working with Congress and the Executive Branch, the proposed Department and NRC recommendations help strengthen the nation.

My enormous gratitude goes to Dr. Tom Kirlin for directing the work of our Center in this area and for coordinating these meetings and this report.

David M. Abshire
President
June 2002

OBSERVATIONS AND RECOMMENDATIONS

1. **To fight terrorism and build a better peace, we need to invest in "Dual Use" R&D projects and the public health infra-structure:**
   A. Investments in the public health infrastructure will improve overall medical care.
   B. Investments in research often have civilian as well as military applications, and these innovations will strengthen the economy, provide a better quality of life and improve homeland security.

2. **We need to recognize that the risk of another bioterrorist attack is real and growing:**
   A. Warfare has changed. States used to have a monopoly on large-scale violence that political institutions regulated. Now, individuals and groups can wield weapons of mass destruction, like anthrax, which can be more powerful than a hydrogen bomb.
   B. The Soviet Union trained 7,000 scientists in biological warfare, many of whom are now unemployed. Iraq has an active biological warfare program and armed 100 bombs and 15 missiles with a botulism toxin during the Gulf War.
   C. Registering lab workers will not ensure public safety—pathogenic organisms are obtained readily from any sick person, animal, sewage, burial site or laboratory.
   D. Anyone with access to the Internet and a basic understanding of chemistry can set up a biological weapons lab in a small room for less than $80,000.

3. **We need to recognize that we are ill-prepared:**
   A. Congress has allocated $3 billion to fight bioterrorism in 2002 and passed the Bioterrorism Preparedness Act, which the President should sign and agencies should implement.
   B. The President has requested an additional $5.9 billion in 2003 and has delegated authority to the Department of Health and Human Services. The National Institute of Allergy and Infectious Diseases (NIAID) has created a bioterrorism response plan and the National Institutes of Health have developed a research plan.
   C. These decisions and funds will upgrade the public health system, increase the number of doctors, nurses and other first responder capabilities, and enable hospitals, police and others to better coordinate information.
   D. However, the U.S. also needs to:
      - ▶ Make zero tolerance the global policy objective on bioterrorism.
      - ▶ Marshal the best minds in science to improve counter-terrorism technologies, reform the Food and Drug Administration approval process of new drugs, and engage in cutting-edge research on bioterrorism vaccines.
      - ▶ Improve our ability to gather and analyze intelligence information.
      - ▶ Engage in a public diplomacy campaign aimed at making zero tolerance the global standard for allies and adversaries.
      - ▶ Better educate individual Americans about bioterrrorism.

4. **We need a public/private research model that mobilizes the private sector:**
   A. Change from the WWII research model, which recruited a large pool of scientists to turn abstract knowledge into military weapons, to a new research model that recognizes that most technologies now are in the public domain, so the challenge is to turn "Radio Shack" technologies into protective devices that reduce the vulnerability of our transportation, mail, food, information, energy and communication systems.
   B. Set priorities: should we be developing antibiotics for natural diseases or pharmaceuticals to respond to bioterrorist threats?

5. **We need to better utilize research universities so that we produce:**
   A. Vaccine stockpiles.
   B. Corps of trained physicians able to assess new drug use in life threatening circumstances.
   C. A greater number of U.S. citizens with the necessary political and social insight and linguistic and cultural knowledge to help fight global terrorism.

PUBLIUS AWARDS SPEAKER

William Frist

Bill Frist was elected to the United States Senate from Tennessee in 1994, filling the seat once held by Andrew Jackson. He serves as head of the National Republican Senatorial Committee, Senate liaison to the White House, and one of the two Congressional representatives to the United Nations General Assembly. Senator Frist is a recognized authority on public health and health care issues and has worked closely with Democrats as well as Republicans on legislation to improve health care delivery and remove roadblocks to its accessibility. In 2000, he worked with Senator Ted Kennedy to substantially increase funding to improve the federal response to bioterrorism and strengthen the Centers for Disease Control. Frist is the ranking member of the Senate Public Health Subcommittee and the Subcommittee on African Affairs. He also serves on the Subcommittees on International Operations & Terrorism and Near Eastern & South Asian Affairs. He was elected Deputy Whip in 1999. Frist graduated from Princeton University and Harvard Medical School, then spent several years in surgical training at Massachusetts General Hospital, Stanford University Medical Center, and in England, before joining the teaching faculty at Vanderbilt University Medical Center in 1985. There, he specialized in heart and lung transplant surgery, then founded and subsequently directed the internationally renowned Vanderbilt Transplant Center.

CAPITOL HILL PANEL PARTICIPANTS

Joshua Lederberg

Joshua Lederberg is Professor *Emeritus* and past President of the Rockefeller University and devoted to biomedical research. Dr. Lederberg was educated at Columbia and Yale Universities, where he was a pioneer in the field of bacterial genetics with the discovery of genetic recombination in bacteria. In 1958, at the age of 33, Dr. Lederberg received the Nobel Prize in the Physiology of Medicine for this work and subsequent research on bacterial genetics. Dr. Lederberg was a professor of genetics at the University of Wisconsin and at the Stanford University School of Medicine before he arrived at The Rockefeller University in 1978. Since 1990, as a Sackler Foundation Scholar, he has resumed his laboratory research in molecular genetics; he is also a Consulting Professor at Stanford's Center for International Security and Cooperation. Dr. Lederberg has had a special and long-standing interest in control of and defense against microbiological weapons. Along with Dr. Robert Shope, he co-chaired a study for the Institute of Medicine, National Academy of Sciences, resulting in the book, *Emerging Infections: Microbial Threats to Health in the U.S.*, which has had wide circulation in the technical community in this country and at the World Health Organization. More recently, Dr. Lederberg edited *Biological Weapons: Limiting the Threat*.

John H. Marburger III

John Marburger is Science Advisor to the President and Director of the Office of Science and Technology Policy. Before his appointment in the Executive Office of the President, he served as Director of Brookhaven National Laboratory from 1998, and as the third President of the State University of New York at Stony Brook (1980-1994). He came to Long Island in 1980 from the University of Southern California where he had been a Professor of Physics and

Electrical Engineering, serving as the Physics Department Chairman and Dean of the College of Letters, Arts and Sciences in the 1970's. In the Fall of 1994, he returned to the faculty at Stony Brook, teaching and conducting research. Three years later, he became President of Brookhaven Science Associates. During his presidency, Dr. Marburger served on numerous boards and committees, including chairmanship of the Governor's commission on the Shoreham Nuclear Power facility. Dr. Marburger received his Bachelor's in Physics from Princeton University and his Ph.D. in Applied Physics from Stanford.

Homer A. Neal (Chair)

Homer A. Neal, a Center Trustee, is Director of the University of Michigan-ATLAS Project, the Samuel A. Goudsmit Distinguished University Professor of Physics, Interim President *Emeritus*, and Vice President *Emeritus* for Research at the University of Michigan. From 1987 to 1993, he was Chair of the University of Michigan Physics Department. He served as Vice President for Academic Affairs and Provost at the State University of New York at Stony Brook from 1981 to 1986, and as the Dean for Research and Graduate Development at Indiana University from 1976 to 1981. He has served as a member of the U.S. National Science Board, a Regent of the Smithsonian Institution, and on the Boards of Argonne National Laboratory, Oak Ridge National Laboratory; and the Fermi National Accelerator Laboratory. Dr. Neal's research area is in experimental high-energy physics and he currently conducts his research at CERN, the European Laboratory for Particle Physics where his research group is part of the ATLAS Experiment. He is a recipient of the Sloan Foundation Fellowship, the John Simon Guggenheim Fellowship, the Stony Brook Medal, and the Indiana University Distinguished Alumni Service Award. He is the author of two books and over two hundred technical papers. Dr. Neal received his B.S. degree in Physics, with honors, from Indiana University and his Ph.D. in Physics from the University of Michigan.

William Schneider, Jr.

William Schneider is Chairman of the Defense Department's Defense Science Board, President of International Planning Services, Inc. and Adjunct Fellow at the Hudson Institute. From 1982 until 1986, he served as Undersecretary of State for Security Assistance, Science & Technology, before which he was the Associate Director for National Security and International Affairs at the Office of Management and Budget. Dr. Schneider served as Chairman of the President's General Advisory Committee on Arms Control and Disarmament from 1987 until 1993. He is Chairman of the Department of State's Defense Trade Advisory Group and a consultant at the Department of State, Department of Defense, and Department of Energy. Dr. Schneider has published numerous articles and monographs on defense and foreign policy, U.S. strategic forces, theater nuclear forces, and unconventional warfare, as well as three books, the most recent being *Arms, Men, and Military Budgets*. Dr. Schneider received his Ph.D. from New York University, from which he also received the Founders Day Award.

"MARSHALLING SCIENCE RESOURCES FOR THIS WAR AND A BETTER PEACE"

Remarks by
Senator Bill Frist, MD
2002 Publius Award Recipient
April 11, 2002

TODAY, WE FACE A FACT THAT NONE OF US IMAGINED seven months ago, the use of an innocent germ—anthrax—as a weapon of mass destruction. And it didn't have to be anthrax, it could have been smallpox or tularemia or the plague. So as a nation, we are more vulnerable today to bioweapons than to any traditional means of warfare.

When a terrorist uses a biological agent as a weapon, their goal is to cause an outbreak of an infectious disease. Anthrax is an infectious disease. Smallpox is an infectious disease. Tularemia is an infectious disease. Ebola is an infectious disease. These terrorists don't want to kill one person. They want to kill hundreds or hundreds of thousands of people, and they can do that by releasing a biological agent and causing an outbreak of infectious disease.

Hearings on Bioterrorism

Three years ago I held a series of hearings on bioterrorism, at which I said: "As a nation we are currently more vulnerable to bioweapons than any other traditional means of warfare, and if we are easy targets for bioweapons, we really do need to examine why that is the case and what we can do to defend ourselves against these agents and to reduce what we all recognize is that inherent vulnerability."

The enormity of this threat is hard to imagine. Just five months ago, more than 10,000 people were placed on antibiotic treatment to protect against anthrax. This nation was paralyzed and staff members who worked on Capitol Hill were panicked because some had gotten anthrax on their clothing and didn't know if it would kill them, or, if they went home, whether they would infect their own families and cause their death. The terrorists accomplished what they set out to do, and that is to personalize terror. They took our daily lives, our infrastructure, and turned them upside down.

Anthrax

Here is what anthrax looks like. Those little chains there are the anthrax bacteria, which many of you in the audience have seen. This is the specimen from the cerebral spinal fluid of the first person killed in a bioterrorist attack on the United States of America. The big round cells are white cells. This is 2002, and this is something we all need to be thinking about, including the U.S. Senate.

This germ or bacteria is more powerful than a hydrogen bomb. Are we prepared to handle this terrorist attack on our nation? The facts suggest that on October 14th or 15th we

PUBLIC HEALTH SYSTEM GAPS BEFORE SEPTEMBER 11

- 9 of 10 public health departments did not have staff trained in bioterrorism
- 1/3 departments serving 25,000 or fewer people had no internet access and 1/4 of all public health staff have no e-mail
- Less than 1 percent of food imports were inspected

were very unprepared, and—I'll be very careful here—we are now much better prepared but not as prepared as we might be.

Take another example—smallpox. Are we really ready to quarantine large segments of our population? Can we use the same public policy in terms of vaccinating people as we have used before? Are hospitals prepared, given that only one out of five hospitals had ever prepared for a bioterrorist attack before October 15th? The risk is real, not hypothetical. Seven months ago, Senator Kennedy, myself and a few others held hearings on this vulnerability that people said was hypothetical, but it is a reality now.

The Risk is Growing

Moreover, the risk is growing. Why do I say that? Because the letter that was sent to Senator Leahy was even more toxic than the one that was sent to Senator Daschle. Our national intelligence agencies, the CIA and FBI, tell us that the biological warfare capabilities of state and non-state actors are growing worldwide. This means that the risk of an attack against the United States and it's allies will increase in the coming years. The risk is real, the risk is increasing.

This germ is more powerful than a hydrogen bomb.

I want to impress upon American people the reality of our situation. The threat of bioterrorism is real; it is increasing; and our vulnerabilities remain high. And although we are not unprepared for a future attack, we are under-prepared.

This means that the demands on us are growing. Suddenly we are at the intersection of foreign policy, public health, science, technology, and the ethics of our response. Iraq is a good example of the challenges we face. In 1985 Iraq launched a biological warfare program that, ten years later, our inspectors discovered had produced more than 19,000 liters of botulism toxin. Botulism toxin is the most powerful poison today. About 10,000 liters were put in munitions, including one hundred bombs and 15 missiles during the Gulf War. Would Iraq do it again? I don't know. Our inspectors are not there. Yet Iraq has the scientific capability of doing so, and we know that they have used chemical weapons against their own people.

Iraq is not alone in having this capability. Russia possesses the world's largest, most sophisticated biological weapon program—7,000 scientists have been trained in biological warfare. These are the best scientists in the world. Their goal, like our National Institutes of Health, is to take the very best minds and to support their research, but Russia's goal during the Cold War was to develop offensive biological weapons.

IRAQ

- ▶ Launched robust bio-program in 1985
- ▶ Produced 19,000 liters of botulism (10,000 liters in munitions) and 8,500 liters of anthrax (6,500 liters in munitions)
- ▶ Gulf War: weaponized 100 bombs and 15 missle warheads with botulism; 50 bombs and 10 missle warheads with anthrax
- ▶ Can deliver bio-agents from aircraft and has also equipped helicopters for crop spraying anthrax spores
- ▶ Used chemical weapons on its own people

RUSSIA

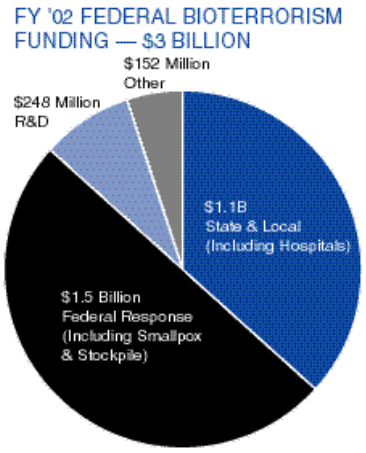
- ▶ The world's largest bio-program with 7,000 scientists
- ▶ Smallpox, anthrax, plague, botulism toxin and Ebola
- ▶ 20 liters of smallpox in 1980
- ▶ Weaponized plague for use in ICB missles

Now many of those 7,000 scientists are unemployed. The fall of the Soviet Union left many of these scientists unable to make more than a few dollars a day. Yet these individuals have enormous intellectual capacity—and anyone who wants to can set up a biological weapons lab for about $50,000 to $80,000 and create anthrax in a room that measures eight by ten feet.

Anthrax, of course, is not the only potential weapon of mass destruction. In the history of mankind, smallpox has killed about 400 million people. And many of you in the room tonight, scientists and public health officials, wiped out smallpox. As a disease, smallpox no longer exists anywhere in the world, yet we are more vulnerable today than we were 50 years ago. Why? Because we know that in 1980 the Russians had 20 liters of smallpox, and they are not alone. And because those immunizations on your arms are really not effective today, and no natural immunity is being developed. The risk is real, the risk is growing.

How do We Become Less Vulnerable?

I believe that the key to becoming less vulnerable starts with improving our public health system. Frankly, we've under-invested in our public health system for the last 15 years. Three years ago, Senator Kennedy and I wrote a bill to improve the public health system, and the bill was passed. But we couldn't even convince our colleagues that they needed to adequately fund our public health system. Then an anthrax letter mailed to the Senate in October personalized terror. We learned the hard way that we didn't know enough, and we learned to admit it. The Bioterrorism Preparedness Act is one way we can respond. This bill passed the United States Senate in December. It passed the House of Representatives in December as well. Now the House and Senate have worked out differences, and the President is expected to sign the bill shortly.



So legislation is one effective response by government to bioterrorism. Funding is another, especially increased funding to our public health infrastructure. The President, Secretary Thompson and Governor Ridge are providing leadership. Those of us in Congress are providing funding, which went up $3 billion in December, and now the President proposes allocating $6 billion to help reduce our vulnerabilities to bioterrorism. But we also need to marshal our scientific and technical resources and challenge the very best minds to help meet this threat to our nation.

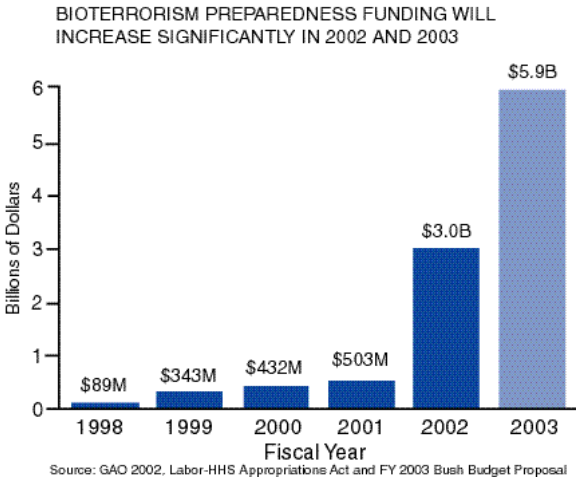
The pie chart shows how the $3 billion will be spent. The largest area represents the federal response, led by the National Institutes of Health. NIH sends 80% of those dollars to the great research universities. It is going to take the great private institutions working in partnership with the public institutions to meet the challenges not only of anthrax, but of smallpox, the Ebola virus, and the plague. Each challenge is different. We know that Russia had an active Ebola program; we know that Iraq had an active Ebola offensive biological weapon program. Now, I can tell you as a scientist that we don't really know very much about Ebola virus except that it is contagious and has a 90% mortality. We don't know why it springs up, or why it goes away, so we've put our smartest people at the National Institutes of Health to look at those

BIOTERRORISM PREPAREDNESS ACT

- ▶ Ensuring Coordination and Accountability
- ▶ Enhanced State and Federal Funding
- ▶ Food and Agricultural Safety
- ▶ Enhanced Regulation of Biological Agents and Toxins
- ▶ Increased Training of Health Professionals
- ▶ Incentives for Research and Developement (Treatments, Assays, Vaccines)

germs and diseases so that we can better protect people.

That's the scientific challenge. Now, the real political challenge was to get everyone to agree to dedicate at least one third of the overall funds—the $1.1 billion in the second largest area—to local public health officials. They are the one's who are going to respond if there's another attack. Getting money to the local level was not easy, it took a bipartisan, non-partisan approach, but we did it.



Developing Integrated Response Models

We also need to develop integrated response models because doctors and nurses and public health officials are going to be the first responders, not necessarily the policeman or the rescue squads. But many doctors have not been trained to look at smallpox or anthrax or Ebola, and we need to fill that gap in the public health infrastructure.

Suppose you manufacture 300 million doses of smallpox vaccine, but the terrorist simply moves down his list to anthrax or tularemia or some other weapon of mass destruction.

We need the intelligence community to help us assess this risk, and to identify individuals who might use these weapons. And we need to be prepared for real civil unrest and a possible breakdown of government. So in the same room you need to put a police officer next to a doctor, next to an epidemiologist, next to a nurse, next to a public health official, next to a microbiologist, and have them communicate around the table. It just doesn't happen. Now, in 2002, we realize the importance of an integrated model, a model that calls upon the scientist who may not have even left the microscope. But if that scientist cannot communicate in an effective way with that law enforcement officer, or local public health officials, the system will fall apart.

But even those steps will not be sufficient. In truth, we need to empower individuals. We need to give them the information that they will need to deal with these new threats to our society. And the place to start is in the K-12 education system, teaching students that math and science can have immediate, personal value as well as enable us to do the research needed to fight bioterrorism.

Dual Use Benefits

Dual use is another important concept. If we spend $3 billion and even another $6 billion and we don't ever see another bioterror attack, was the money spent a good investment? I would argue that it is. It prevented another attack—and we invested in our public health infrastructure. Investing in appropriate science and our communities is a good idea. Every year about 20,000 Americans die from the flu. A better public health system will lower that number. The same is true of food poisoning. Every year 5,000 people die from food poisoning, and nearly 1,000 people are hospitalized daily.

DUAL-USE INVESTMENT

- ▶ Bioterrorism
- ▶ 20,000 people die per year from flu
- ▶ Reemerging infectious disease
- ▶ Nearly 1,000 people are hospitalized every day for food poisoning
- ▶ 5,000 people die from food poisoning per year

Clearly, when we invest locally in fighting bioterrorism, we will get the added benefit of being better able to treat the flu and fight HIV/AIDS and other emerging infections.

I don't wish to frighten people, but intelligence briefings tell us that at least 11 countries and perhaps as many as 17 countries have developed offensive biological weapons programs. Six months ago, we only had 15 million doses of smallpox vaccine. Under the leadership of Secretary Tommy Thompson, we will soon have a sufficient number of smallpox doses to protect our country against this disease, should a smallpox attack occur.

We are better prepared than we once were, but in 2002 we have a long way to go and we will need to follow a systematic approach. Funding is needed, yes, as is legislation. But we also need to marshal our scientific and technical resources for this national initiative, and we need to educate people about the vulnerability and how best to respond.

Marshalling S&T Resources

Bioterrorism is new. It is strange to many people who haven't thought about it. But scientists have had to think about it, and we need to marshal the best minds in science to fight bioterrorism. We also need to apply technology where possible, such as in the areas of surveillance and diagnostics. For example, we need to call on venture capitalists in the private sector to finance the development of surveillance equipment that is capable of detecting whether anthrax has been introduced through a ventilation system.

We need to marshal the best minds in science to fight bioterrorism.

We need to detect smallpox early, before it spreads, rather than wait 15 or 16 days for the first signs, as we now must do. And we need to merge the interests of our Food and Drug Administration with our National Institutes of Health and the Defense Advanced Research Project Agency (DARPA), which led the R&D effort throughout much of the Cold War.

The federal government can't, and shouldn't, try to do it all. Partnerships are needed among the public and private sector, and among private sector companies. These partnerships among pharmaceutical companies have already given us some of the very best medicines and vaccines. But we also need education. Physicians who have never seen smallpox might be slow to recognize it. A parent who looks at the pictures in my book might be much quicker than that physician.

Education and Communications are Key

My goal is to empower individual Americans with knowledge, because knowledge is one of our best defenses against bioterrorism. If anthrax hits or smallpox hits or the plague hits and people know what to do, they won't panic and paralysis won't set in. We will be able to contain the threat. These are the immediate benefits of a better educated and more empowered people.

Communication and coordination are also critically important. Germs can't be smelled, they can't be seen, they can't be heard, unlike a gun or an airplane crashing into a building. Every moment counts, so the place to start is surveillance and then communication and then response—backed by research, drugs and vaccine. We need to improve communication in the event of a terrorist attack. One-third of health departments serving 25,000 or fewer people doesn't have internet access and one-quarter of all public health staff doesn't have email. Both the public and the private sectors need to invest more in the development and proliferation of communications infrastructure.

To win the war on terrorism, we must do more than fight it on the battlefield; we must wage it with the collective talent and energy of every American. That is what it took to defeat Nazi Germany, Fascist Italy and Imperial Japan in World War II. That is what it took to tear down the Iron Curtain, defeat Communism and end the Cold War. And that is what it will take to wipe the evil scourge of terrorism from the Earth.

The place to start is surveillance and then communication and then response.

At the end of the day, there is going to be a winner and there's going to be a loser in the war on terrorism. And the loser will suffer the consequences of defeat. To win the war, we must not be complacent. We must not think of this war as a traditional battlefield with soldiers and airplanes. And we must not wage war only with our soldiers. To win this war, we must marshal the talent and energy of every American, and all of our national resources, our government, our academies, our institutions, our industries, and, yes, each of us as individuals. Only then can we win this war, and, as after the last war fought on our soil, forge a just and lasting peace.

"BRIDGING THE GAP BETWEEN POLICY & RESEARCH"

Remarks by

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Capitol Hill

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DR. HOMER NEAL: Science and technology are an integral part of the fabric that determines the health, welfare and security of our nation. Their pervasive nature, cutting across academe, industry, health and defense illustrates why they must command the attention of the President, even in times of relative normalcy, and especially in times of national stress.

Since Presidential leadership is the primary focus of the Center for the Study of the Presidency, today's dialogue on national science policies, and the extent to which they are being implemented or need updating, is indeed timely.

Last evening, Senator Frist spoke on marshalling science resources for this war and for a better peace. Senator Frist pointed out that we are indeed vulnerable to bioterrorism and other terrorist acts, and that the risks are growing. He noted, somewhat chillingly, that a single event, a single bioterrorist event, could have more impact than an atomic bomb. Marshalling was a key word that he used several times. By that he meant pulling together the intellectual resources of universities, of industry, healthcare workers, the military, all to better prepare us, to strengthen us against the kinds of attacks that have been contemplated.

We'd like to extend the dialogue today by discussing how the research community and the federal government might better bridge the gap between policy and research programs in order to better marshal our resources. Our focus is on long-range research, but the speakers have been invited to focus on one or more facets of that relationship. Let's start with comments by Dr. John Marburger, Director of the Office of Science and Technology Policy.

DR. JOHN MARBURGER: When I saw the title, "Bridging the Gap Between Research and Policy," it reminded me of an exchange that took place between a friend of mine, who was a candidate for a Rhodes Scholarship, and the examining committee. One of the interviewers asked him to name the greatest distance that he could think of. Being a physicist — now he's an astronomer — he said a mega parsec, which is quite a large astronomical distance. But the interviewer then asked: "Is that greater than the distance between the mind and the heart?"

The gap between policy and research is like that. Both research and policy are multidimensional enterprises, and not easily compared, but let me try. Recently I've been quite interested in how one shapes policy to make a difference, and particularly how we prepare the nation to respond effectively, not only to this war against terrorism, but to future challenges to the nation's security. Policies that drive long-range research are going to be rather different from policies that drive short-term research for this war, which is my focus today.

World War II Research

As you know, President Bush declared a war on terrorism shortly after September 11th. This war is being conducted in a very different technical context than was World War II. As World War II began, some of the major theoretical and conceptual discoveries of the early 20th century were just beginning to have an impact on technology. Quantum mechanics was in its infancy, or, at most, its adolescence. Nuclear fission, which would play an important role in World War II, had been discovered a year before work on it was classified in this country. The federal government focused its attention on exploiting this very abstract and conceptual knowledge to create such devices as radar and nuclear weapons, and, as rapidly as possible, on turning theoretical knowledge into something that could be deployed on a battlefield. It wasn't until after the war that venture capitalists and entrepreneurs developed the electronics, chemical, pharmaceutical, laser and optical industries.

As WWII began, the federal government exploited very abstract knowledge by launching a massive recruitment program.

The federal government launched its World War II research initiative with a massive recruitment program aimed at scientists working in fields relevant to radar, nuclear science, and the like. These scientists were gathered together in large, federally-funded laboratories and put to work on rather specific problems that were well defined, oriented toward a war theater, and implemented by people who were trained to deal with the technologies developed in these laboratories.

R&D Today

Today's situation is entirely different. The war against terrorism is taking place at a time that is not only rich in technological devices and concepts, but at a time in the history of science and technology when much of this knowledge and technology is in the public domain. The real challenge is to deploy this technology to meet the challenges of terrorism.

To be sure, some areas of inquiry, such as bioterrorism, require additional basic research, but, in my opinion, much of this research is likely to be short-term. The broader challenge is to turn existing technologies into devices to protect ourselves, and to strengthen those systems that are vulnerable to terrorist exploitation. For example, we need to develop devices that can detect explosives and ensure that terrorists don't carry some sort of weapon into our airports or send something through the postal system. So, certainly, there's a role for research in these endeavors.

But these can't be really long-term research programs, because our need to strengthen our systems is immediate. The real challenge, in short, is not to develop new technologies from conceptual science but to better understand how we can deploy available technologies in our war against terrorism. Doing so won't be easy. Unlike conventional wars, this war isn't being conducted on a map where you can draw battle lines and identify territory that's under your control and territory that's under the control of the enemy. It's extremely difficult to draw a map of the war on terrorism. We don't know how to locate, in advance, key elements or participants in this war, or how to tell when we've gained control over a "territory" and made it invulnerable to terrorism.

Indeed, the federal government doesn't often own or control the systems that we need to strengthen, and all are poorly defined—mail, transportation, the transport of electricity, food and information. These systems are not managed by federal employees, and the tools that we have to influence behavior and to reduce the vulnerability of these systems, are quite limited. Our society wants it that way. People don't want an intrusive command and control response to the war against terrorism because imposing such a system would deprive, or at least diminish, the very civil liberties and freedoms that we are struggling to preserve in our war against terrorism.

The broader challenge is to turn existing technologies into devices to protect ourselves.

So, regardless of what technical or scientific capabilities we may possess, we are having a hard time defining the problem precisely, and then implementing a strategy to reduce our vulnerabilities.

Facing An Asymmetrical Threat

This is quite a turn of events. Typically, in a military campaign, you specify the threat and then identify the kind of technology you need to meet that threat. You define parameters and set up a procurement process to purchase the weapons system that you want. In the war against terrorism, defining the threat is not easy, and it's going to be awhile before we specify what kinds of systems will help prevent terrorism from wreaking havoc on our society.

So, while a lot of technology is available for this war, the situation is much more complicated than it was at the outset of World War II. However, we are not at a complete loss. We do have technologies to detect hazardous materials. We can compare information from different sources and distinguish between correct and false information. This said, in my opinion we are going to have difficulty effectively deploying these and other technologies so that we fill the gaps in our defenses and reduce the vulnerabilities in our systems.

In short, the way we use technology to fight against terrorism is going to be quite different from the way we fought World War II, and we will develop that technology for a much more complicated setting than the conventional battlefield. Moreover, it's going to take us awhile to develop a strategic approach that adequately matches the complexities of the terrorist world.

Let me just conclude by noting that research and analysis is not only needed to create and deploy anti-terrorists weapons, but a comparable R&D initiative is needed to bet-

POLICY ISSUES FOR THE FUTURE

- ▶ Learn more about germs and diseases
- ▶ Develop models of response that integrate the public health, emergency medical response, and law enforcement activities
- ▶ Fill gaps in the public health infrastructure
- ▶ Enhance public-private partnerships

ter understand how we should implement our strategic plan in this fight against terrorism. The social scienctists, and, indeed, the political scientists, have something to say about implementation. How government agencies and capabilities are organized is itself an interesting question, one which Administration officials are debating even as we engage various policy-making organizations in this war against terrorism. There is by no means agreement about how the war against terrorism should be organized, although the President, I believe, has a clear vision of what he wants. It's a responsibility of people like myself to try to figure out how to respond to the President's direction, given the mechanisms that are available to us in government.

DR. JOSHUA LEDERBERG: Ever since I began my research career in medicine 55 years ago, I've been concerned about possible abuses of medical knowledge, a concern that was particularly frightening in light of the fact that my own research focused on genetic manipulation of microorganisms. This field of research has resulted in very, very large benefits, but it can also be easily perverted and result in significant abuse.

Today, biological weapons of mass destruction are readily at hand, and can come from any sick person, or animal, or sewage, or burial sites and, of course, laboratories. Pathogenic organisms are to be found in all of these places. So people who think that we're going to ensure our safety by registering or putting constraints on who can work on anthrax in the laboratory are simply oblivious to the natural distribution of every other pathogen that you care to name.

No one can stop dissemination of the knowledge needed to be a bioterrorist.

This change in the weapons of war has resulted in a major, asymmetrical shift in power. States used to have a monopoly on large-scale violence, and so we needed political institutions to regulate that use of violence, and, insofar as an anarchic world would allow, to limit the use of violence between states. That situation has now been overtaken by the new technoterrorism, and particularly by bioterrorism because anyone with a minimal education in biological and microbiological science can greatly amplify insidious acts of violence, and do so easily. What these individuals don't know already can be found in many books, on the internet, and in many other places. No one can stop the dissemination of this knowledge.

Zero Tolerance: The Overarching Policy Goal

Our overarching policy goal must therefore be a global regime of zero tolerance on the use of biological weapons, in any circumstance. This also must be our immediate strategy of self-defense, for civilization is at stake, and many countries who might be tempted to use biological weapons for some immediate, short-term goal need to be convinced that their future is in peril if they institutionalize this new power or harbor dissident individuals who want to use biological weapons.

The first step is convincing ourselves that this imperative is the only option, especially in light of 9/11 and the anthrax attacks last October. The second step is to realize that the enormous threat of biological weapons is not yet adequately incorporated into our allocation of resources, or even at the necessary level into our technical and political deliberations. This is true in our own country, as well as around the world. But we've certainly taken a major step in the right direction. We have convinced ourselves that this new imperative is real and that we need to expend appropriate fiscal, diplomatic and military capital in order to realize our overarching policy goal of zero tolerance for biological weapons. We have also begun the task of convincing our allies, our friends, our onlookers and our adversaries that this is really very, very serious business, and that we are determined to do all that is necessary to make the use

of biological weapons illegal and to ensure that a global system is in place to punish those who even consider using such weapons.

To be effective, the United States has to come to the table with clean hands. We cannot be seen as proceeding with the development of our own biological weaponry. To avoid such charges, we will need greater transparency in the oversight of experiments that could have dual-use (i.e. civilian and military applications). Such experiments can easily be misinterpreted as a new avenue or direction for developing biological weapons.

Reaching the objective that I propose also means—and this is perhaps the most important message—vastly improving public diplomacy among our friends, onlookers and adversaries. We must convince them that our campaign to delegitimize biological weaponry is in the global interest. As I talk about biological weapons on several levels, I will come back to this point about public diplomacy, so I hope you will bear with me and make the necessary connections.

The Changing Nature of Warfare

Let's start with the changing nature of warfare. In recent months, our military forces have been used in new ways. In Afghanistan the goal is regime change, not the destruction of a nation. We want to protect enslaved civilian populations who happen to live within the boundaries of our targets. In such situations, collateral damage is as harmful as friendly fire, and we must use our tools carefully to reach our political objectives without turning regional pacification into a global, ethnic conflict. I believe that the United States earned a B+ or better in the recent campaign, probably far exceeded the expectations of many, many pessimists, but we can do still better. Above all, we need better intelligence, more common sense in the interpretation of that intelligence, and unremitting attention to how and where our weapons were used and to the technology that ensures that we hit the intended target, not something or someone else. Improving these weapons requires the development of a research agenda that focuses on effects-based operations. Our military services are just beginning to explore this new field of research in a disciplined way.

Above all, we need better intelligence, more common sense in the interpretation of that intelligence, and unremitting attention to the technology that ensures that we hit the intended target.

We're also discovering that our public diplomacy and intelligence capabilities are thin at best in many regions of the world. We don't have people on the ground with the necessary linguistic skills, knowledge of political institutions, knowledge of Islamic sects, and cultural insight to help free the Iraqi people from their captor, Saddam Hussein, so of course we have never penetrated any of these organizations. We need to think very hard about whom we might train and send to gain intelligence about Iraq's political situation and its biological weapons program. And we need to do the same for other countries or groups that may pose a threat.

In 1957 we responded to the Sputnik challenge with substantial reinvestment in technical education. We are in a similar situation today. Polls in the Middle East, Greece, Europe and elsewhere make clear that some people think that perhaps the U.S. got what it deserved on September 11th. Such remarks suggest that we face a crisis analogous to Sputnik. Even more ominous are the voices in this country who might shrug off such statements, saying they really don't matter. So what we need is an intelligence gathering and public diplomacy campaign comparable in intensity to the renewed emphasis placed on technical education in the

late 1950s and throughout the 1960s. The demand is rising sharply for people with this kind of social insight, political insight, linguistic skills and area knowledge, and here the universities can play an important role. Where else are you going to inculcate those skills and abilities?

Vast Improvement in the Past Six Months

Now let's turn to the technical side of biological weapons. We have made vast improvements in our defense capabilities during the past six months. The allocation of additional funds and the delegation of authority to the Department of Health and Human Services, and to the National Institute of Allergy and Infectious Disease in particular—NIAID—are particularly encouraging signs. We also have complied a list of threat agents, including anthrax, plague, tularemia and smallpox, and researchers ought to concentrate first on this list. The NIAID response plan is excellent. It's too detailed to go into it here, but you can readily find it on their website, www.niaid.nih.gov. I strongly recommend this site to any of you who want to better understand bioterrorism. The Centers for Disease Control and Prevention also has an excellent site, www.bt.cdc.gov. You will find excellent information there on policy and technical issues.

The NIAID website contains a document, released about a month ago, that outlines the U.S. counter-bioterrorism response plan. This plan has removed a certain ambiguity regarding the role of the Department of Defense in our counter-terrorism initiatives. DOD appears to be the only place with sufficient history, resources, discipline and logistical capabilities to conduct a war on bioterrorism. Certainly it would be the nation's last resort in the event of any major threat. However, directors of various departments who are charged with obtaining funding for the war in Afghanistan, or for meeting short-term and long-term equipment needs, or for training and so forth, are naturally competitive. So it has taken a little time to identify the major policy elements regarding civilian protection against bioterrorism weapons, and who will be responsible for the public's health. The decision now has been made to give that responsibility to the Health and Human Services Agency, which is going to have to take on a slightly more military cast in order to accomplish its objectives. Of course, continued collaboration and coordination among all federal departments and agencies remains very important to meeting this challenge.

We have made vast improvements in our defense capabilities during the past six months.

NIH Bioterrorism Research Plan

The National Institutes of Health bioterrorism research plan is very straightforward. It didn't take long to identify the key elements because they are identical to the research agenda we need to follow on infectious diseases in general. For example, we need to understand the biology of the microbe; the host response; how to make, test, validate and produce vaccines; other possible therapeutics, such as antibiotics; how to find more antiviral agents of which there are very few; which diagnostic tools work; how to detect threat agents and diseases early; what research resources are available, including the training of research specialists and responders; how well our physical infrastructures, our laboratories, can contain agents such as smallpox, which are too dangerous to handle in any but the most highly contained structures; and how accessible are costly—and, therefore, necessarily shared—technologies, animal models, reagents and cell lines. Implementing this agenda means directly engaging the academic community, which is eager to apply its skills to our national challenge.

GENERAL RECOMMENDATIONS

The following recommendations apply to all areas of NIAID counter-bioterrorism research.

Immediate Research

- ▶ Develop regional Centers of Excellence for Bioterrorism and Emerging Diseases Research.
- ▶ Expand the capacity to conduct phase I, II, and III evaluations of candidate vaccines and treatments for agents of bioterrorism.
- ▶ Expand non-human primate capability to evaluate new therapeutic and vaccine products.
- ▶ Attract new scientific disciplines to counter-bioterrorism research, and expand the research training of a new cohort of investigators.
- ▶ Expand extramural and intramural research and clinical infrastructure, including construction and renovation of BSL-3/4 laboratories.
- ▶ Expand the availability of animal models for preclinical research.
- ▶ Develop rapid, inexpensive, and broad-based clinical diagnostics approaches using genomics and proteomics.
- ▶ Encourage structural genomics and proteomics research for the targeted development of drugs, vaccines, and diagnostics.
- ▶ Encourage industry participation to ensure the availability of rapid, sensitive, and licensed diagnostics to hospital clinical laboratories.
- ▶ Expand partnership opportunities with other agencies and governments.
- ▶ Develop a centralized repository for reagents and clinical specimens for agents of bioterrorism.
- ▶ Develop procedures and GMP facilities capable of producing monoclonal antibodies, vaccines, and other immunotherapies for phase I and II clinical studies.
- ▶ Enhance adjuvant discovery and rational design of Toll system mediators.
- ▶ Identify and characterize innate and adaptive immune responses that occur after exposure to agents of bioterrorism and enhance basic research on mucosal immunology.
- ▶ Establish MHC/peptide and B-cell epitope databases that may be used to further define immune responses, including the identification of relevant immune polymorphisms, and maximize such responses.

Reconnecting the Public and Private Sectors

University researchers are also in communication with the policymakers and implementers in the public and private sectors. Communication is not an issue, but legacy problems do exist, especially the cost of implementing an abundant number of ideas. So I agree with Jack Marburger that the United States faces significant obstacles in the deployment of technologies that already exist. But I don't believe that we have all the basic science knowledge that we need in order to find the most efficacious remedies.

In fact, scientists are stumbling about, pretty much in the dark, about how to treat anthrax. We are stumbling about on what the best measures would be for the introduction of smallpox vaccines. We also don't know how long we dare postpone the introduction of large-scale vaccination in the face of an imminent bioterrorism attack, knowing that when you do, immuno-compromised people will be at grave risk from the vaccine itself. So some basic scientific questions still demand answers.

Several days ago I participated in a meeting in which people argued about where,

Intermediate and Long-Term Research

- ▶ Examine human genetic variation in response to therapy, in drug susceptibility, and in infectivity.
- ▶ Define the human microbiome in states of health and disease.
- ▶ Develop predictive immunology tools that will allow for the design of interventions for currently unknown biological weapons.
- ▶ Analyze unique responses at the genome level to infection with agents of bioterrorism.
- ▶ Analyze gene expression of agents of bioterrorism in vivo.
- ▶ Standardize and validate protocols that involve studies using animal models.
- ▶ Expand clinical capacity for phase I safety studies.
- ▶ Develop, test, and analyze novel vaccination and protective strategies in all populations (e.g., the very young, the elderly, and immunocompromised individuals).
- ▶ Enhance currently available international capability by expanding existing clinical trial networks (e.g., the International Collaborations in Infectious Disease Research Program).
- ▶ Address human resource needs required for supporting research through training grants, fellowships, travel grants, and faculty development.
- ▶ Define the genetic basis of host susceptibility to infection with agents of bioterrorism.
- ▶ Identify pathogen-induced immunoregulatory and immunosuppressive effects that influence the host's ability to mount an effective immune response and respond to post-exposure vaccination or immunotherapy.

exactly, anthrax spores germinate in the lung. Do they germinate in the lung fluid, or do you have to have macrophage cells take them up into those cells before that germination will occur and the disease process will start. The answer to that questions is key to developing an effective therapy and to managing that disease in relationship to other lung diseases. We know that it takes, on average, about 10,000 anthrax spores to infect an individual, although probably only one finally does the job. However, we don't know why it takes so many spores. That basic knowledge just doesn't exist. Our ignorance is understandable. It is a rare disease, and it only comes to our attention today in the context of bioterrorism, so anthrax has not been a very popular object of biomedical research.

A National Academies of Science, Engineering and Medicine project, instigated by, and reporting to, Jack Marburger, is now examining in detail what our S&T agenda should be. For the most part, this report parallels the NIH plan, but some additional items are missing that reflect special functions outside the purview of NIH. For example, the National Academies stress the importance of epidemiological modeling and surveillance; of having sensors and people in place to compile and analyze information that might indicate the abnormal occurrence of disease; and recognition of unfamiliar diseases when they first occur in a community. That's the province of the Centers for Disease Control and Prevention. CDC has not fared well as policymakers decide how best to allocate funds, even though that agency is at the forefront of protecting public health.

So much for the good news, which I've qualified in a few places. Clearly, we need uninterrupted communication and constant coordination among all of the government

AREAS OF RESEARCH EMPHASIS

The following areas have been identified by NIAID as priorities for counter-bioterrorism research.

Biology of the Microbe

Research into the basic biology and disease-causing mechanisms of pathogens underpins efforts to develop interventions against agents of bioterrorism. NIAID supports research to better understand the microbial components that define a pathogen's life cycle, as well as the events or processes that are critical to initiating infection or influencing the severity of disease. This knowledge is crucial to the development of preventative and therapeutic strategies. An important tool in understanding the basic biology of pathogenic microbes, including potential agents of bioterrorism, is the ability to rapidly obtain genome-sequencing information about these agents. The application of genomics research, coupled with other biochemical and microbiological information, is expected to facilitate the discovery of new targets for diagnostics, drugs, and vaccines. Comparative genomics (comparing the sequences of different strains of particular organisms) will be a particularly important component of future research, helping us to understand virulence and pathogenicity factors.

Host Response

Research into both innate and adaptive immune responses is critical in the development of interventions against agents of bioterrorism. We must define pathogen-triggered protective and deleterious immune responses to inform the development of products aimed at controlling and preventing disease. The identification of innate immune receptors and the functional responses that they trigger will enable targeted activation of the innate immune response and induction of specific adaptive immunity. Only one adjuvant (alum) is currently approved for general vaccine use. Therefore, we need new immunostimulatory agents. To develop new tools for disease control, we need a more detailed understanding of signaling pathways, of compartmentalization of immune responses, and of pathogen-specific immunoregulation. Little is known about the ways that immune responses can vary among different individuals according to age, general health status, treatment with immunosuppressive drugs, and genetic makeup. An enhanced understanding of these variables and their impact on immunity is critical for the design and development of effective vaccines and immunotherapeutics.

Vaccines

Vaccines are the most effective method of protecting the public against infectious diseases. New and improved vaccines against agents of bioterrorism must be suitable for civilian populations of varying ages and health status. In addition, vaccines developed to counter civilian bioterrorist attacks must be safe, easy to administer, and capable of an immediate protective and/or transmission-blocking immune response. Scientists must develop and characterize adjuvants that can enhance these desirable characteristics. Basic research on the host immune response, including correlates of protection and the basic biology of the microbe, will enhance vaccine development efforts. The initial focus at NIAID has been on the development of vaccines against smallpox and anthrax. However, the development of candidate vaccines for other category A agents remains a priority. A critical component of efforts to achieve these goals is enhanced linkages and partnerships with industry.

Therapeutics

In the event of a bioterrorism incident, we will need effective therapeutics to address the immediate health needs of the public. Antimicrobial agents for treating many infectious diseases currently exist. However, we need a broader, more robust arsenal of anti-infective agents to treat the broad civilian population and to intervene against drug-resistant variants that may emerge. Detailed knowledge of the pathways that are essential for replication and pathogenesis will enhance drug development. However, many diseases caused by category A agents do not provide adequate economic incentives for the development of therapeutic or preventive measures by industry. Therefore, collaboration between industry and government will be needed to produce the next generation of anti-infectives. Another priority is the development of monoclonal antibodies with activity against toxins or other critical virulence factors.

Diagnostics

A successful response to a bioterrorist threat requires diagnostics that can identify the pathogen involved. However, the initial clinical signs and symptoms of many agents considered biothreats are nonspecific and resemble those of common infections. The ability to rapidly identify the introduction of a bioterrorism organism or toxin will require diagnostic tools that are highly sensitive, specific, inexpensive, easy to use, and located in primary care settings. Ideally, these tests also could be used to evaluate the possible spectrum of antimicrobial resistance. We have the theoretical means to design and develop such assays. For example, microchip-based platforms containing thousands of microbial signature profiles could be developed. A centralized database could be constructed to collect this information and allow the rapid identification of unusual patterns or clustering anywhere in the country. Functional genomic tools to identify multiple organisms simultaneously will be important, as will enhanced linkages and partnerships with industry.

Research Resources

Basic research and the development of new vaccines, therapeutics, and diagnostics depend on the availability of research resources. Among the resources needed to conduct counter-bioterrorism research are genetic, genomics, and proteomics information; appropriate in vitro and animal models; validated assays to measure immune and other host responses; and standardized reagents. In addition, research with potentially deadly category A agents must be conducted in appropriate containment facilities and must follow procedures that eliminate the threat to laboratory and clinical personnel and adjacent communities. Access to biosafety level (BSL) 3/4 facilities, particularly those with the capacity for animal model and clinical research, is limited and must be expanded. Expertise in a wide variety of areas, including structural biology, ecology, medicinal chemistry, bioinformatics, the development and humanization of antibodies, diagnostic validation, and therapeutic and vaccine candidate production, is needed. NIAID understands that a “goal oriented approach” to developing countermeasures against bioterrorism agents will require new collaborations between basic scientists, process development scientists, and engineers to quickly transition vaccine and therapeutic candidates into clinical testing. In addition, enhanced relationships among NIH, academia, and industry will be necessary to produce clinical material that meets good clinical practice requirements. NIAID’s research agenda will include the training of a new cohort of investigators, the physical infrastructure within which to conduct this research and production, and the technologies, animal models, and reagents necessary to pursue this line of research and clinical testing.

departments. The fact that they are at least starting to openly talk to one another is an encouraging sign. That has not always been the case.

Mobilizing the Private Sector

How best to mobilize the private sector is of greater concern, especially the pharmaceutical and biotechnology sectors. A number of groups are looking at this issue, including the Center for Strategic and International Studies and a roundtable at the National Academy of Sciences.

But right now our vaccine and antibiotic development system is broken, and broken in several places. No one is setting priorities in the race between the development of antibiotics to resist natural disease and the need to develop new pharmaceuticals to respond to bioterrorist threats.

The industry has retreated because of market considerations and the enormous complexity of the regulatory process.

Some short-term answers are being patched together to meet immediate procurement needs, and private companies are collaborating in that effort. For example, several companies are producing stockpiles of existing vaccines. But there are less than a half-dozen major pharmaceutical companies in this country that are involved in making vaccines in any way. The industry has retreated from this field because of market considerations and the enormous complexity of the regulatory process, much of which undoubtedly is necessary, but which, in certain circumstances, is a case of the best being the enemy of the good.

Genomics, a new technology, has created a reservoir of promising antibiotics. However, these candidates are still in the discovery pipeline, and it's a long haul to get them through the FDA validation gauntlet under current procedures. It can cost several hundred million dollars to gain approval for each drug. Given this costly system, few innovations are going to be validated. They're just not affordable, and they don't provide attractive targets for the kind of creative and competitive investment needed for further development.

Reforming the FDA Approval Process

Can we construct a better system? I think we can. In times of crises, we should be able to set aside the patriarchal system, where everything has to be proven to asymptotic perfection before anybody is allowed to use it, and make room for the exercise of informed judgment and transparent argument. Unfortunately, the current system of approval overrides that exercise of judgment. This system may be appropriate when, once a drug is approved by the FDA, any M.D., regardless of their qualifications to appraise the data presented, can prescribe it.

To prepare for a possible biomedical crisis, I recommend that the FDA reform its approval process—and that we reform the medical education system so that a cadre of certified prescribers, who have the judgment and background experience equal to FDA regulators, is available to make life-saving decisions when the public's health is endangered. This system would allow us to use vaccines and drugs that have not gone through a full $300 million worth of clinical testing, but have progressed far enough to have scrutinized them very closely. As noted, this system requires that a corps of physicians be trained and qualified to assess when a new drug should be used.

Well, we're not going to settle this issue this morning, and unhappily the gap between the pharmaceutical industry and federal policy is confounded by the battle scars both sides received during arguments over the price of drugs and other issues. I pray that those battles

will not slow or cloud the way we deal with the very real threat of bioterrorism.

[During his review of this manuscript, Dr. Lederberg noted that on May 30, 2002, "the FDA announced new procedures for validating the effectiveness of drugs and vaccines to be used in the management of mass casualties from bioterror. It is manifestly impossible to conduct clinical trials for the indication they are labeled for, namely, a bioterrorist attack. It will therefore be permissible to use animal models, and a scientific foundation of the mechanism, to validate such medications for efficacy. Safety for humans will still be validated by the same cautious trails as have governed drug approval to date. This decision on the use of drugs and vaccines to manage mass casualties from bioterroism, long overdue, is to be applauded."]

DR. WILLIAM SCHNEIDER: Because I am now serving as chairman of the Defense Science Board, I will talk about bridging the policy and research gap from a Department of Defense perspective, and with a very practical task at hand, namely, identifying the science and technology requirements for dealing with counter-terrorists.

We need a cadre of certified prescribers who make life-saving decisions when the public's health is endangered.

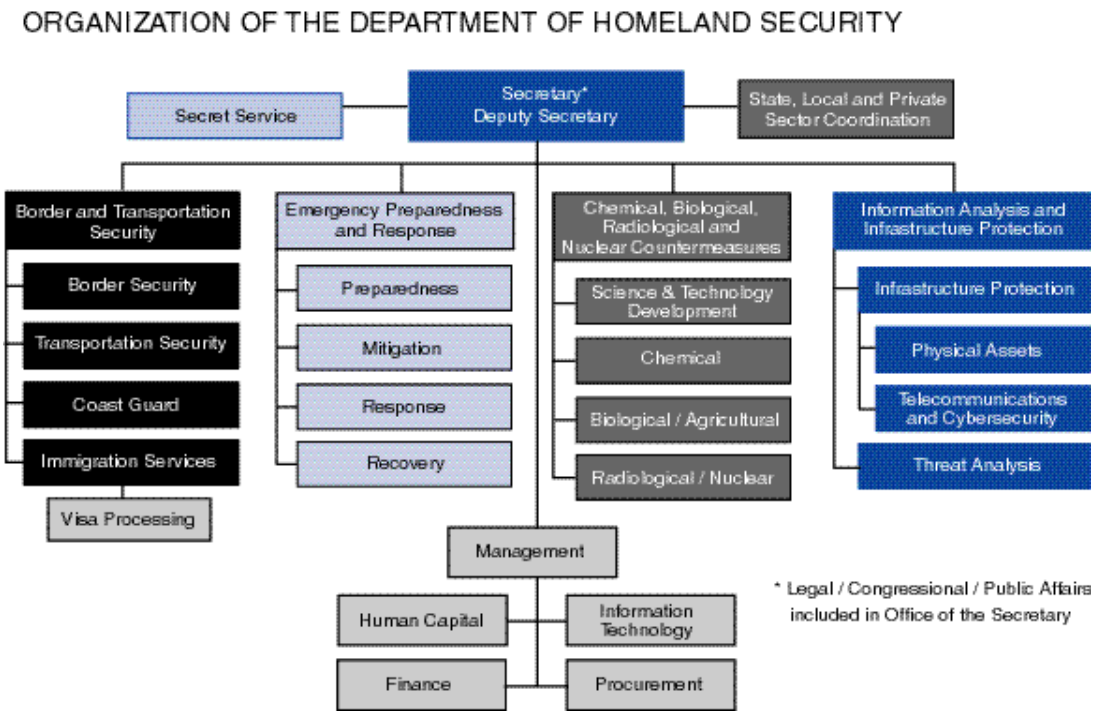
The President and Secretary Rumsfeld recognize that we need to think about post-Cold War threats differently than we did about Cold War ones, when we sought to optimize our military response to a specific threat. We had a very good understanding of the nature of the Soviet threat, and our information systems that tracked the evolution of that threat were very finely tuned, so we were able to respond in a more-or-less optimum way. Things are quite different today. We cannot accurately forecast a specific threat, especially in the current technology environment, so we cannot optimize our use of force.

Moreover, because the enabling technologies for advanced military capabilities are no longer produced in the defense sector—they are by and large produced in the civil sector—government must concern itself with technology trade. We want to license and monitor the export of sophisticated technologies to limit their use against us.

Radio Shack Technology

Our core military competence consists of using systems engineering and systems integration skills to convert technologies that are widely, and even universally, available, and applying that technology in a clever way to military applications. In some ways it's the difference between being a cook and a chef. This skill is increasingly important, and now accounts for perhaps 5% to 10% of the total cost of defense products. This number sounds small, but this skill lends a crucial advantage to our military capabilities, and indeed is a core competence of the U.S. defense industry.

Let me offer a recent example. You recall that during the conflict in Afghanistan the United States scored a significant technology victory: we used an unmanned aerial vehicle, the Predator, to track individual terrorists and strike them. This accomplishment rests entirely on the integration of what you might call Radio Shack technology. All we really did was install a conventional, commercial TV camera in a Predator, which gave us pretty good images of the ground, clean enough, anyway, to identify specific targets. Then, using the kind of digital data that goes into digital maps to support the backpacking industry, we were able to geo-register the precise coordinates of a particular target by sending them through a routine commercial communications satellite. We then bounced those coordinates down to a Global Position Satellite receiver in the tail of a 2,000 pound bomb, which had just been dropped from a B-52 whose original design was more than 50 years old. And we did all of this in real time—even



though it involved either obsolescent or mundane, universally available technology. The breakthrough was in the way the entire system was engineered, and the decision to apply this technology in this way to this kind of target.

This example also illustrates why terrorism is a serious problem. Increasingly, the basic technology for terrorism and counterterrorism is universally available. Moreover, the knowledge needed to turn technology into dangerous weapons is widely disseminated. So our technical challenge is not to develop weapons against a particular country or set of countries, but to figure out how modern technology can be turned into a weapon, then developing the ability to defeat or defuse the use of that technology against us. Professor Lederberg has already listed a number of threats—bioterrorism, nuclear terrorism, chemical weapons. I would add that terrorists, and states that support terrorists, are increasingly able to access the systems needed to deliver these weapons of mass destruction.

Human Intelligence and Special Forces

The Department of Defense is also focused on another key issue: collecting, processing and disseminating intelligence that can give us a much better idea of the evolution of a particular threat. As Secretary Rumsfeld has said, long-gone are the days when you could plan your defense around known threats. Today, you need capabilities-based planning—and not just good but exquisite intelligence—because you have to react much more quickly as a threat evolves. Modern warfare requires new technologies, and the ability to move quickly at the cutting edge of technology in order to counter threats.

Special operations forces have also successfully utilized modern technology on the ground in Afghanistan. However, the advanced technology that these troops used is generally available in the commercial sector, so the value we have added is in being able to engineer an integrated system and to apply it to solve specific military problems. Finally, the Defense Science Board recently published a six-volume study on homeland security that may interest

Excerpt from the President's June 6, 2002 proposal to create:

THE DEPARTMENT OF HOMELAND SECURITY

Science & Technology Agenda. In the war against terrorism, America's vast science and technology base provides us with a key advantage. The Department would press this advantage with a national research and development enterprise for homeland security comparable in emphasis and scope to that which has supported the national security community for more than fifty years. This is appropriate, given the scale of the mission and the catastrophic potential of the threat. Many of the needed systems would be potentially continental in scope, and thus the technologies must scale appropriately, in terms of complexity, operation, and sustainability.

This research and development would be driven by a constant examination of the nation's vulnerabilities, constant testing of our security systems, and a constant evaluation of the threat and its weaknesses. The emphasis within this enterprise would be on catastrophic terrorism — threats to the security of our homeland that would result in large-scale loss of life and major economic impact. It would be aimed at both evolutionary improvements to current capabilities as well as the development of revolutionary new capabilities.

The following are examples of the types of research and development projects that the Department would pursue with its scientific assets.

- **Preventing importation of nuclear weapons and material.** The Department of Homeland Security would make defeating this threat a top priority of its research and development efforts. This nuclear denial program would develop and deploy new technologies and systems for safeguarding nuclear material stockpiles and for detecting the movement of those materials. In particular, it would focus on better detection of illicit nuclear material transport on the open seas, at U.S. ports of entry, and throughout the national transportation system.
- **Detecting bioterrorist attacks**. The anthrax attacks of October 2001 proved that quick recognition of biological terrorism is crucial to saving lives. The Department of Homeland Security would lead efforts to develop, deploy, manage, and maintain a national system for detecting the use of biological agents within the United States. This system would consist of a national public health data surveillance system to monitor public and private databases for indications that a bioterrorist attack has occurred, as well as a sensor network to detect and report the release of bioterrorist pathogens in densely populated areas.

The technologies developed must not only make us safer, but also make our daily lives better. While protecting against the rare event, they should also enhance the commonplace. Thus, the technologies developed for homeland security should fit well within our physical and economic infrastructure, and our national habits. System performance must balance the risks associated with the threat against the impact of false alarms and impediments to our way of life.

some of you. I believe that this study is on the Defense Science Board website, which you can reach through defenselink.mil.

These are some of the practical ways in which science and technology help support our national security objectives. However, as Dr. Marburger has said, terrorists have focused many of their attacks on the seam between homeland security and national defense, in the broadest sense. And whether you call it political science or government organization or government processes, we have the most difficulty coping with the terrorist challenge at this junction. I won't go into detail on this matter, but suffice it to say that the Department of Defense will likely play a major role, and, in some cases, even an enabling role, as we seek to close this bureaucratic seam in our response to terrorism. But DOD will not be the primary actor—

individual agencies and organizations will be. However, improving the institutional capabilities of some organizations to fight terrorism may require the kind of innovation that we have not seen in perhaps half a century.

DR. HOMER NEAL: I'd like to take a few moments to talk about bridging the gap between policy and research, from the perspective of universities. The term gap suggests that a divide exists between expectation and reality, as perceived from one side or the other. It suggests that a partnership, or an agreement to engage in a partnership, is in need of discussion or updating. I find the paradigm of a partnership to be useful, both in its own right and because of its historical relevance to today's discussion.

Several years ago I led an effort by several universities to engage the federal government and industry in discussions about the future of the university-government partnership. In 1996 we convened a major meeting in Ann Arbor of university and industrial leaders and representatives of government to discuss this topic in the inaugural Wiesner Symposium. The symposium was named for Jerome Wiesner, a Michigan alumnus, in recognition of his role as the first Presidential Science Advisor.

Most of the living Science Advisors participated in the symposium and actively engaged in the exchange. Two members of the House Science Committee—Representatives Vernon Ehlers and Lynn Rivers—served as honorary chairs. Indeed, Congressman Ehlers credited our symposium with providing the impetus for the study that he subsequently launched, and which led to the issuance of the Committee's report, *Unlocking the Future*.

A Changing Partnership

In 1996, we focused on the changing relationship between research universities and the federal government, occasioned by the transition to the post-Cold War era. The prevailing sentiment was that the nation no longer faced a critical military threat from another superpower, so perhaps our government should alter its research relationship with universities. Now, some might think that no link exists between these topics, so the question is meaningless. I assert, however, that they are indeed linked, at least in the minds of many people. An unstated premise of this partnership was that the nation needed to maintain strong ties with its universities, even if it meant supporting activities that were unrelated to national security. The production of a steady stream of well-trained scientists and engineers by our universities was recognized as an extremely important objective. Moreover, given that a breakthrough in any scientific area might quickly end up as a military advantage to one side or the other, we thought that having a broad spectrum of research projects underway at various universities was the best way to maintain technological capabilities, if not superiority in almost all areas.

This line of reasoning produced a very close working partnership among university and federal officials throughout the Cold War. However, at the end of the Cold War those of us in universities began to sense that the government no longer felt the partnership was needed. Many of us felt an urgent need to open a dialogue about the state of this partnership. And I believe we have been largely successful in conveying the importance of an on-going close relationship between the federal government and our univer-

ROLE OF ACADEMIC HEALTH CENTERS

- ▶ Training in bioterrorism and emergency preparedness
- ▶ Training public health workers
- ▶ R&D to create better surveillance systems
- ▶ Developing countermeasures
- ▶ Collaborating with local health departments

sities. Public and private officials now recognize that basic and applied research are key to our national defense and economic growth.

Today, people recognize the relevance of basic research to economic competitiveness. Rapid advances in the biomedical sciences are readily apparent. The information technology explosion also clearly demonstrates how our lives have forever been changed by the Internet, mobile phones and other new information technologies. Of course there have been stumbles along the way. One example is the cancellation of the super-conducting supercollider. The United States spent billions of dollars developing the relevant technology, then ceded leadership to others.

September 11th changed our nation's priorities in a way that is comparable to fall of the Berlin Wall. Indeed, September 11th signals the start of a new war, a radically different type of war, as Dr. Marburger has noted. We are again faced with a transition of deep significance, one which deserves careful examination of its impact on the university-federal government partnership. But these events have also had an impact on every one of us—as individuals who are scientists.

Higgs Boson

Like thousands of other scientists, I asked, after September 11th, what can I do to help? My field is high-energy physics, which has helped miniaturize computers, develop high-speed electronics, create the world wide web, and fostered numerous other inventions. We're often thought of as pursuing some of the most esoteric quests known to humankind. But the question remained, was there anything we could do?

Universities may appear to lag in their responsiveness to national needs but they are key players in the nation's overall response system.

One answer may lie in our quest to find the elusive Higgs Boson, a yet unseen particle which we believe exits and which is required to explain many observed physical phenomena. We know the pattern of responses we expect to receive in our detectors when and if the Higgs makes its appearance. We know how to estimate the number and types of false signals we should receive. We know how to correlate information received from different sensors in the detector. We have invested thousands of person years in perfecting the techniques for searches of such rare phenomenon.

This quest is not unlike looking for a particular individual or event somewhere on the globe. Imagine that the signals from the sensors were just faint whispers and rumors. Imagine that we had ways—and we do—of calibrating the detector to help determine what signals are significant. The parallels are remarkable, and I cite this example only to demonstrate that even obscure fields, such as high-energy physics, may have much to contribute to securing our freedom.

The Federal/University R&D Partnership

The partnership between university researchers and the federal government has never been a static one. In fact, most funding for basic research at universities comes from federal sources. Scientists procure the equipment they need to carry out their research, and support their students and their trainees, because these funds make possible most university research projects. The government also sets research priorities and even topics, with input from federal advisory structures and peer review mechanisms. The federal government also places restrictions on research protocols and established research procedures. In short, policymak-

ers at the national level decide many of the important questions about what research will be done, how the research will be carried out, and how and when the findings will be deployed.

This system works quite well in normal times. The extensive advisory system set up by the funding agencies and other steps, such as peer review, help ensure that the research undertaken will have broad communal support. This process also instills a level of quality control and transparency.

However, this partnership is not a straight jacket. For example, a federal decision to stop research in a certain area may stop such research at all federal laboratories, but this same decision may have only a marginal impact, at least immediately, on university or industry research projects which are funded by non-federal sources.

This loose coupling of federal policies in our universities is a source of great strength in the U.S. science and technology enterprise, but it can cause a degree of difficulty in times of national stress. Universities may appear to lag in their responsiveness to national needs. And while there may be some truth to this perception, universities are nevertheless key players in the nation's overall response system.

Forging a New Partnership

University research may at first not appear relevant to homeland security issues, but nowhere else can one find the depth of understanding, for example, of the biological agents that terrorists may deploy for their purposes. Moreover, universities discovered most of the basic scientific principles that advanced technologies now use in military systems. Similarly, many of the highly trained staff deployed to operate modern military hardware received some part of their training in a university setting. And data acquisition and analysis techniques used in tracking pathogens and intelligence gathering have their origins in university research.

Openness in the university environment and the primacy of the respect for human life sets limits on what kind of research should be done on campus.

Our future ability to anticipate terrorist acts may also rest on our universities, especially on those graduates with broad language skills and a deep understanding of other cultures. In short, universities should not be regarded as bystanders in the war on terror but as key players. Openness in the university environment and the primacy of the respect for human life sets limits on what kind of research can and should be done on campus. Altering the way campus research and teaching is carried out would be most unwise. It's the freedom of ideas and intellectual exchanges that makes universities successful. And the strong links between university researchers and national laboratories and industry provides a powerful mechanism for technology transfer.

Having said this, it is important to note that the number of American students in key science and technology fields is less than the number of foreign students, at both the undergraduate and graduate level. We need to address the matter of why our students are turning their backs on some of the very areas that are so essential to protecting our freedom.

Now, the federal government needs to take a leadership role in convincing students to consider careers in science and technology. It needs to remind our citizens that much of what we enjoy today, in terms of our standard of living and our national security, derives from the support of science and technology. The very prestige of the President should be placed behind this effort. The government needs to make sure that every agency understands the importance of universities in the overall national security framework, and that though universities must have their independence, they can nevertheless be strong partners.

In short, this partnership serves both entities well. But like all partnerships, the participants need to review their understanding and renew their commitment to core principles when the operating environment changes, as it did when the Berlin Wall fell and on September 11, 2001. More than ever, we need to ensure that we train a sufficient number of students, of scientists and engineers, to meet the needs of the nation. We need to ensure that the creativity of our faculty is tapped fully so that we can protect our citizens.

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