American Society for Microbiology:
2004 Annual BioDefense Conference

Dr. John Marburger, OSTP Director
7 Mar 2004

I want to thank Drs. Shenk and Cassell, and the meeting program committee for inviting me to speak at this important meeting's opening session. I've looked over the meeting agenda and see that already today you've had the opportunity to attend several workshops sponsored by the federal research agencies, and get detailed information on what the agencies are planning for their biodefense research programs. I wish I could attend the whole meeting and listen to your exciting research results. This is an important meeting because there is so much to do and we need your help; not only to perform the research, but to help us preserve its use for legitimate purposes.

The anthrax attacks that followed shortly after the tragic events of 9/11 sent two unambiguous messages to the American public and to the President: we are vulnerable to bioterrorism; and we are not prepared. We did not anticipate the delivery of a biological weapon through the U.S. Postal Service and were surprised by how easily the anthrax spores spread. Since that wake-up call, the President has made it a top national priority to protect from and prepare to respond to a broad range of threats, including unprecedented measures to ensure biosecurity and enable biodefense. Much has been accomplished, but even more remains to be done. The recent successful delivery of ricin powder through the postal service has shown that we are still vulnerable, even after the number of measures we have taken to secure the mail. And we know that we have many more vulnerabilities in other aspects of homeland security.

Today, I would like to speak to you about the latest pro-active steps the administration has taken in this effort, working towards stifling the use of biological agents as weapons while at the same time taking every step to preserve the vitality of the critical biosciences research contributing to human welfare.

When I look to the present problems and issues we face together, I am reminded of the problems we face in a time that does not seem so long ago to me -- but as I look out into the audience I realize that it may seem so to some of you. As a boy in the 1950's, I attended the "Atoms for Peace" initiative. Information and visions abounded on the wonders of nuclear

physics, nuclear reactors, and even nuclear munitions, and how all of these (nuclear munitions included) were going to change our world for the better. I was fascinated and inspired by what I saw, and in fact, I eventually became a professor of physics. Yet, even though these innovations were the result of some of the most exciting and fundamental discoveries ever made, it would also be hard to disagree that the potential for misuse and abuse was very real, in fact, very possible. The proper safeguards were, and continue to be, essential.

We have been fortunate that, from the very start of the modern nuclear age, scientists and government worked closely together to ensure the maximum amount of scientific progress while at the same time controlling the flow of information to those who might use it for the purpose of terrorism—arguably, the fate of the free world depended on it. Yet, despite its wartime birth, the eventual proliferation of nuclear weapons technology, and the somewhat shaky history of nuclear energy research and development; our investments in nuclear science have resulted in countless benefits to our society, not just a better understanding of the physical world and its fundamental building blocks, but life-changing and life-saving applications like NMR, MRI, PET and even the radiotherapy of cancers.

In some ways, the evolution of the bioscience is the reverse of nuclear science—and I do not just refer to disciplinary rivalries. The difference is that modern bioscience was born into a "healthy" and open atmosphere; insofar as nobody needs convincing that this research contributes greatly to our wellbeing. Research in the life sciences has resulted in numerous gains for public health, animal health and productivity, and agriculture, and holds many promises for tomorrow. But, it is a grim fact of life that the very same tools developed to better the health and condition of human kind can also be used for its destruction. If we are to ensure the beneficent uses of science, we must also recognize and guard against the potential for misuse. Even more troubling, the infrastructure required to produce a biological weapon is just the smallest fraction of that to produce a nuclear weapon, thus being both easier to create, and harder to detect or monitor.

Therefore, we as a community have been engaged in some hard thinking about how we do bioscience research and about what changes are needed to better safeguard against unintended and destructive uses of our research results. In response to the current bio-threats -- as well as those posed by chemical, radiological and nuclear attacks -- this Administration, under the strong leadership of President Bush, has taken dramatic and unprecedented action, while still adhering

to the principles that will maintain a vigorous international program of research collaboration in the biosciences. Today I would like to highlight the President's brand new Biosecurity Initiative and explain how this initiative will play an important role in the suite of measures being undertaken to improve our homeland and national security.

The Administration is embarking on a series of actions that, taken together, will enhance biosecurity in life sciences research. The newest, within this set of initiatives, is the establishment of the National Science Advisory Board for Biosecurity, or NSABB, within the Department of Health and Human Services. The purpose of this board will be to provide advice, guidance, and leadership regarding biological research that has the potential for misuse and could pose a biologic threat to public health or national security.

But, before I get into the details of the NSABB, let me explain the core beliefs that are the foundation for the US government initiative in this area. Whatever actions we decide to pursue:

- The action should improve security
- The action should allow non-sensitive research to proceed without impedance and sensitive investigations to proceed within specific parameters
- The action should be acceptable to the major stakeholders, who include the scientific community-- government, academia, and industry; the security community; and the international community.

These are the benchmarks against which we evaluate any proposed action or policy. And, as you are major stakeholders in this area, I remind you that you have a major role in helping us evaluate our actions and policies against these benchmarks. In this effort, two way communication is absolutely essential.

You've all heard the old adage "I'm from the government, and I'm here to help"? It always draws a laugh, even though I do believe that being "here to help" is my role between the Administration and the academic community. But, it may surprise you to know that one of the things I really depend on -- a highlight of my job -- are those occasions when one of you comes to my office to say; "I'm from the scientific community and I'm here to help!" Dr. Gerald Fink is here with us tonight and he has certainly done that, and earned our gratitude. He led a project at the National Academies on *Research Standards and Practices to Prevent the Destructive Application of Biotechnology* that published a report and recommendations that this

Administration has taken very seriously. I'll say more about that report and the Administration's response later.

I want one other thing to be completely clear, particularly to this community, before I get back to my main topic today, the NSABB. The US government will continue to support and conduct fundamental research in the biosciences, and considers this research a high priority. An instinctive response to the potential for misuse might be to restrict research activities, knowledge about, or communication of research results. But, we are very much aware of the necessity of continuing an active and vital program. Not only will this research continue to improve life and health at home and globally, but it is essential in the development of detection methods and countermeasures to improve our defenses against biological threats.

Thanks to the consistent, and I should add, *persistent*, efforts by President Bush and key members of the Congress, funding requests for bioterrorism research alone within the National Institutes of Health have increased by nearly an order of magnitude over the course of two years, from $202 million to a request for more than $1.65 billion. Within the Department of Homeland Security, an additional $920 million has been appropriated for biological countermeasures. Funding for the traditional life sciences and biomedical research is also strongly supported.

Most of this research will continue to be conducted in the traditional open and collaborative manner, but some may be restricted or classified for national security reasons; for example, any research whose results would reveal a vulnerability to our current medical countermeasures. We must also strive together to encourage a "culture of responsibility" within the research community. The Administration is relying heavily on you who perform the research to make biosecurity one of your personal goals, to anticipate and identify possible dual use research and results, and to educate yourselves about the issues and the measures that are being put in place to address them.

Now back to the NSABB. I am sure you are aware of the National Research Council's recently published report "Biotechnology in the Age of Terrorism," commonly called the Fink report. As you know, this report made a number of recommendations for enhancing our nation's biosecurity, and they are very much in-line with the actions our Administration is taking. [I assure you, I would say good things about Dr. Fink and this report even if he *wasn't* heading up the panel discussion immediately after my talk. The panel did a careful and thorough job and their recommendations have been invaluable as we implement measures to improve our national

biosecurity.] One of the Fink report recommendations was to create a National Science Advisory Board for Biodefense, designed to facilitate dialogue between the defense and science communities; periodically review the "experiments of concern" and "select agent" list; serve as a resource for interested parties, including journal editors; and advise the government. The Administration's had already begun an examination of the issues and developed elements of the President's biosecurity initiatives before the publication of the NRC report, but recommendations from the report have been thoroughly reviewed and, for the most part, incorporated as the initiatives have been further developed and implemented. The new National Science Advisory Board for Biosecurity will be implemented somewhat differently from the concept proposed in the NRC report, but will accomplish the objectives envisioned by the NRC.

The approach that has been developed for the NSABB represents the collaboration of over 15 federal agencies and Departments engaged in the conduct or oversight of life sciences research. It is being established within the Department of Health and Human Services because of the prominent role of this Department in this area. It will have up to 25 voting members who will be appointed by the HHS Secretary in consultation with the heads of relevant federal departments and agencies. Members will represent the broad range of scientific expertise necessary to address biosecurity issues including molecular biology, microbiology, infectious diseases, laboratory biosafety and biosecurity, public health/epidemiology, health physics, pharmaceutical production, veterinary medicine, plant health, food production, bioethics, national security, biodefense, intelligence, law and law enforcement, and scientific publishing. The board will also include *ex officio* members from, at minimum, 15 relevant federal departments and agencies. The board will be managed by the National Institutes of Health.

I'm sure, in this august body, that there are people here who will be asked at some point to serve on the NSABB. If you are interested in being a future member, you'll want more details; and I hope the rest of you will forgive me if I digress into some of the more mundane logistics of the board's operations. The board will meet at least quarterly, and may also be convened on an as-needed basis. If necessary, the NSABB may establish subcommittees, call upon the expertise of special consultants and *ad* hoc working groups, and/or convene conferences, workshops, or other activities as the board sees fit to help accomplish its mission.

Since the NSABB is established in accordance with the Government Sunshine Act and the Federal Advisory Committee Act, all meetings of the NSABB will be publicly announced in

the Federal Register and will be open to the public except as determined by the Secretary of HHS. The meetings will be held, records kept, and annual reviews prepared and filed as required by the applicable laws and the Department policies. If a meeting or meetings should be declared closed to the public, the annual report will, at minimum, contain a list of the members and their business addresses, the NSABB's functions, dates, and places of meetings, and a summary of the activities and recommendations of the board.

The NSABB charter is for two years, subject to renewal by DHHS. Members will be appointed for overlapping terms of two to four years; with terms of more than two years contingent upon the renewal of the charter. Votes of the board can only be held when a quorum is present, which is designated as a majority of the eligible voting members. Members disqualified from any particular vote, for instance by a conflict of interest, shall not be counted towards achieving the quorum. Each committee member shall be paid the nominal amount of $200 per day, plus *per diem* and travel expenses, unless that member is an employee or officer of the U.S. Government, in which case no compensation will be received. The annual costs of running the board -- inclusive of travel, expenses, and staff support -- are not expected to exceed $450,000 *per annum.*

Now, with the administrative details out of the way, what is the role of the NSABB? The board will advise all federal departments and agencies that conduct or support life science research. It will recommend specific strategies for the efficient and effective oversight of dual use biological research, taking into consideration both national security concerns and the needs of the research community. This includes strategies for fostering continued rapid progress in public health research, such as new diagnostics, treatments, vaccines, and detection methods, as well as in food and agriculture research, while simultaneously being mindful of national security concerns. In addition, the board will advise on specific experiments under certain conditions:

- When a proposal has been denied by the Institutional Biosafety Committee, or IBC, and the institution seeks additional guidance for interpretation and application of the guideline; and
- When specific experiments exemplify a significant or particularly complex permutation of an existing category of dual-use research or represent a novel category of dual-use research that requires additional guidance.

In this way, the board will function in a manner similar to the Recombinant DNA Advisory Committee. NSABB recommendations on the performance of such experiments will be transmitted to the IBC, the head of the federal department or agency that conducts or supports the research, and the Secretary of HHS. The board itself, however, will have no authority over the performance of such experiments.

I want to emphasize that the board will not review or be required to approve all dual-use research. The Institutional Biosafety Committees will remain the first level of review for experiments of concern. These committees are already in place at over 400 institutions in the United States, as they are mandatory at any institution receiving NIH funding for research with recombinant DNA, and have been adopted by a large number of facilities voluntarily. The use of the IBC's is not only an intelligent use of resources that are already in place, but is of great utility in that the timing of the review at the very earliest stages in the research process minimizes the possibility of inadvertent dissemination of any potentially adverse information. The NSABB advises on national policies governing local review and approval processes, including the development of guidelines for the case-by-case review and approval by IBC's. It will also develop criteria and processes for the referral of classes of research or specific experiments to the NSABB for guidance. But, NSABB will review and provide guidance on specific experiments only insofar as the already mentioned special circumstances exist. The board will also advise on requests submitted by research institutions for the interpretation and application of the guidelines in instances where the institution seeks additional advice.

There are a number of initial tasks the NSABB will be expected to take on. One initial task will be to develop criteria for identifying dual-use research and research results and also to develop guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results. In this context, "dual-use" encompasses biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. Examples of dual use research will likely include genetic manipulations of organisms that can result in new pathogens; increased pathogenicity; resistance to an antibiotic use to control disease in humans, animals, or crops; altered host range of a pathogen; increased transmissibility of an infectious agent, and/or the ability to escape diagnosis or detection. Dual use research could also encompass studies that yield information about how to increase the lethality of a toxin; manipulations of threat agents

that might impair vaccine effectiveness; and ways to enable the weaponization of a biological agent or toxin.

A second task will be for the board to recommend a code of conduct for scientists and laboratory workers that can be adopted by federal agencies as well as by professional organizations and institutions engaged in the performance of life science research. The board will also develop or recommend programs for education and training in biosecurity issues for all scientists and laboratory workers at federally funded institutions. It is critical that the research enterprise adopt a culture of responsibility over these issues. The Administration recognizes that it has limited ability to influence research performed overseas or in the private sector in institutions not receiving support from a federal agency. But, it is hoped that the activities of the NSABB in advising federal agencies will engage the international scientific and publishing communities and encourage adoption of curricula and codes of conduct by professional societies and institutions.

The NSABB will advise on a number of other issues including working with the scientific community, including journal editors, to ensure the development of guidelines for the publication and public communication of potentially sensitive research; guidelines for local review and approval processes for dual-use biological research; strategies for coordinated international oversight of dual-use biological research; and any other issues as directed by the Secretary of HHS.

Having now explained the NSABB, what it is and what it will do, It is appropriate and important to put the establishment of this board into a larger context-- a series of that Administration's actions that, taken together, will enhance biosecurity in life sciences research. We have already taken a number of critical steps to control access to certain disease causing agents and to limit the public availability of information that can be used to create a biological weapon.

On October 9, 2001, just days after the infamous events of that September, the President established, by Executive Order, the Office of Homeland Security, and asked Governor Tom Ridge to lead it. The new Office had the mandate to develop and co-ordinate the implementation of a comprehensive national strategy to secure the United States from terrorist threats or attacks.

Just over one year later, in an extraordinary re-organization, President Bush signed into law the “Department of Homeland Security Act of 2002” which created the Department of

Homeland Security. The following January, Governor Ridge was sworn in as Secretary of the new department, and within weeks all or part of 22 different agencies came under one organizational roof, with a budget of $30.4 billion in Fiscal Year 2004.

I feel it is important to note that the shape of the new department, especially its technical infrastructure and supporting research and development functions, was strongly influenced by the input of the scientific community, *via* the findings of two reports. First was 2002's "*Making the Nation Safer: the Role of Science and Technology in Countering Terrorism*," created under the auspices of the National Academy of Sciences. This report made numerous recommendations in nine areas related to terrorism and its effects, including human health and agricultural systems, and has since been an invaluable and oft-consulted resource. The second report was prepared by PCAST--the President's Council of Advisors on Science and Technology, which I was honored to co-chair with Fred Kvame—"*Maximizing the Contribution of Science and Technology within the New Department of Homeland Security*."

As I have already noted, the President has also committed significant funds to science and technology within the DHS. Some of the FY2004 programs of the DHS that I'm sure have been of interest to this audience include:

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

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

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

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

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

That last program, *Project BioWatch,* is a major interagency initiative. It has been through a commitment of an entire range of federal agencies that three interagency initiatives

focusing on bioterrorism have been developed: *Project BioWatch; Project BioSense;* and *Project BioShield.*

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

Project BioSense is still in its infancy. It is intended to reduce the lag time between the detection of a possible bio-agent and an appropriate response. Distinct from Project BioWatch, but integrated in function, Project BioSense relies upon multiple streams of information to facilitate rapid decision-making. The parameters monitored will include environmental data from Project BioWatch, epidemiological information from hospitals administered by the Department of Defense and the Veteran's Administration, reports from pharmacies across the nation, and other sources of relevant syndromic and non-traditional data. All of this information will converge at CDC's *Biointelligence Center*, first for analysis, and then, if warranted, for coordinated response. Having this single center examine data from many different sources allows for the detection of patterns and anomalies that may not be apparent through other means. Moreover, the CDC has long been entrusted with both gathering information from and disseminating information to front-line health-care providers. This new role is a logical and well-deserved extension of that mission, in which the CDC will work hand-in-glove with clinicians at the local level to determine if an emergency response is warranted, and the necessary magnitude of that action. I think all would agree that the CDC's exemplary response to the recent phenomenon of SARS demonstrates its strength in precisely this role.

Finally, *Project BioShield* was unveiled by President Bush in his State of the Union address in January 2003. Then, with the enactment of the Homeland Security Appropriations Act the following October, the President granted a total of $5.6 billion to fund Project BioShield

through Fiscal Year 2013, with $890 million appropriated for Fiscal Year 2004. This project has three primary provisions: *first*, Project BioShield will spur the development and procurement of "next generation" medical countermeasures—including vaccines, drugs, and diagnostics—against biological, chemical, radiological, or nuclear agents through special contract authority; *second*, the Act authorizes the National Institutes of Health through the National Institute of Allergy and Infectious Diseases to facilitate promising areas of research in medical countermeasures to these agents; and *third*, it establishes a new emergency use authorization for certain medical therapeutics not yet otherwise approved.

All of these initiatives might be described as *preparedness programs*. There is also a need for what I would call *prevention programs*. In June of last year, President Bush signed into law the *Public Health Security and Bioterrorism Preparedness and Response Act*. This law was designed so as to increase security in those facilities that hold significant amounts of biological agents enumerated on one of two lists: the CDC's *select agent* list discussed previously; and the *high consequence pathogen* list maintained by the USDA's Animal and Plant Health Inspection Service (APHIS). While the CDC list concentrates on human pathogens, and the USDA's on agents affecting plants and animals of commercial importance, a significant number of agents can infect both animals and humans and thus are found on both lists. These are consequently referred to as *overlap agents* in the legislation.

The new law *requires registration* with the CDC or USDA for facilities possessing these enumerated agents. These include: research laboratories, both academic and commercial; clinical diagnostic laboratories if they are holding specimens past the time-frame needed to render diagnosis—30 days extendable to 60 days; and teaching facilities *if* the samples in question are kept in a viable form.

In addition to registration, the law *requires that facilities provide physical security measures* based on a site-specific threat assessment and risk analysis that takes into account the nature of the agents in question and their containment requirements; the need for access; the type of research being conducted; the physical plant and its location; and a host of other factors.

The Administration is doing everything within its power to keep America the world leader in science and technology, while at the same time not placing its citizens at undue risk of having those innovations fall into the wrong hands. We want to do everything possible to balance the needs of public safety with the requirements of good science. It's our plan to

continue to involve the scientific community in our deliberations and planning processes as much as possible. We will continue to rely on the National Academies for advice and review, including continuing to consult and implement the recommendations in the Fink report, and we will look to professional societies such as yours for input, review and comment. New policies and procedures take some getting used to and often require some tweaking before they achieve optimal results. We are very interested in hearing from you about how things are working and what situations arise or questions you have.

And with that, I would be happy to address any questions you may have today.

Thank you.