



Supporting Organizations:



Agenda

April 25, 2006

8:00 – 8:15 Welcome & Introduction by the Conference Chair
Frank M. Rapoport, *Partner*, McKenna Long & Aldridge LLP

Keynote Address:

8:15 – 9:15 THE SENATE’S PLANS AND PRIORITIES: THE BIODEFENSE AND PANDEMIC VACCINE AND DRUG DEVELOPMENT ACT
The Honorable Richard Burr, Senator (R-NC)

This keynote address will report on the Senate’s legislative efforts to bring more and better biodefense and pandemic countermeasures to the market faster—describing its key provisions and their intended impact.

9:15 – 9:45 *Morning Refreshment and Networking Break*

9:45 – 10:30 THE NATION’S BIO-CHEM DEFENSE AND PANDEMIC VACCINE AND THERAPEUTIC DEVELOPMENT FRAMEWORK: AN OVERVIEW OF THE CURRENT PROCESS
Bill Helming, *Lead Partner, Biodefense and Public Health Practice*, PRTM Management Consultants LLP

This overview will look at the challenges in the government's end-to-end process of developing bio-chem defense and pandemic vaccines and therapeutics. It will outline the current process for carrying out R&D, conducting clinical trials, establishing and scaling up manufacturing capacity, and stockpiling inventories. It will also look at the complexities of effectively integrating the process and discussion some of the policy challenges in doing so.

- Funding the end-to-end, including the “valley of death”
- Moving products through clinical trials
- Scaling up manufacturing capacity
- Stockpiling inventories
- Dealing with changing priorities

Bio-Chem Defense and Pandemic R&D Plans and Opportunities

10:30 – 11:15 BIODEFENSE AND PANDEMIC RESEARCH OPPORTUNITIES AT THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)
Michael Kurilla, M.D., *Director, Office of BioDefense Research Affairs and Associate Director for BioDefense*, National Institute of Allergy and Infectious Diseases, National Institute of Health

NIAID is the key civilian government agency conducting biodefense and pandemic vaccine and therapeutics R&D. Armed with a sizeable research budget, NIAID R&D priorities are moving from basic research to the development stage—opening up new opportunities to participate in this new area of focus. This session will provide a current update on NIAID research activities.

- What are the current priorities for research and product development?
- What candidates are nearing licensure?
- What type of research proposals is NIAID currently seeking?
- How are the proposals screened and what is the timeline?
- What are the opportunities for industry partnering?

11:15 – 12:00 BIO-CHEM DEFENSE RESEARCH OPPORTUNITIES AT DOD
Col. Joseph Palma, *Deputy for Chemical and Biological Defense Programs and Medical Director*, Department of Defense

The Department of Defense is also conducting research in biodefense vaccines and therapeutics-backed with significant funding. The DOD mission is to develop these countermeasures to protect the warfighter. This session will provide a current update on DOD research priorities and activities.

- What are the priorities for research and product development at DOD?
- What research is currently being conducted?
- How are candidates transitioned to advanced developers?
- What type of research proposals is DOD currently seeking?
- How are the proposals screened and what is the timeline?

12:00 – 1:30 *Group Luncheon*

*Building a Bio-Chem Defense and Pandemic
Vaccine and Therapeutic Industry*

1:30 – 3:00

Industry Panel

INDUSTRY'S PERSPECTIVES ON BUILDING A PROFITABLE AND VIABLE
BIO-CHEM DEFENSE AND PANDEMIC VACCINE AND THERAPEUTIC
BUSINESS SECTOR

Moderator: **Frank M. Rapoport**, *Partner*, McKenna Long & Aldridge LLP

Panelists:

Kim Bush, *President, Vaccine Division*, Baxter Bioscience

John Dong, M.D., Ph.D., *President & Chief Scientific Officer*, GenPhar

Fuad El-Hibri, *Chairman and CEO*, Emergent BioSolutions Inc.

Lance Gordon, Ph.D., *President & CEO*, VaxGen

Daniel Jacobs, CPCM, CMC., *Chairman/CEO*, The Federal Market
Group/Government Business Solutions

Keith Steward, Ph.D., *Vice President*, EMD Pharmaceuticals

The Government's success in building a ready stockpile of effective bio-chem defense and pandemic vaccines and therapeutics rests on its ability to engage the participation and support of pharma and biotech companies—and ultimately on its ability to bring about a viable and profitable biodefense and pandemic vaccine and therapeutic business sector. This panel of pharmaceutical and biotech industry CEOs will discuss the conditions that must be in place to garner industry commitment.

- What role are pharma and biotech companies willing to play in establishing a robust bio-chem defense and pandemic industry for vaccines and therapeutics?
- What are the key requirements that must be met to secure their support in this endeavor?
- How do the Government's efforts to date stack up against these requirements?
- What other actions will the government need to take to address industry requirements?

3:00 – 3:30

Afternoon Refreshment and Networking Break

Stockpiling Bio-chem Defense and Pandemic Vaccines and Therapeutics

3:30 – 4:15 A STATUS REPORT ON THE DEPARTMENT OF HOMELAND SECURITY’S MATERIAL THREAT ASSESSMENTS
John Vitko, Ph.D, *Director, Biological Countermeasures,* Department of Homeland Security

As pharma’s product decisions must be based upon on large-term market potential, they have an obvious interest in the Government’s future plans for purchasing bio-chem defense and pandemic vaccines and therapeutics. DHS has been given the role to determine which threats constitute a Material Threat to our national security and hence may be eligible for BioShield procurement. This session will provide an overview and status report on DHS’s material threat assessments and describe how they are used in the subsequent BioShield processes.

4:15 – 5:00 A STATUS REPORT ON THE PLANS AND ACTIVITIES FOR STOCKPILING BIO-CHEM DEFENSE AND PANDEMIC VACCINES AND THERAPEUTICS
Robin Robinson, Ph.D., *Senior Project Officer for Influenza,* Department of Health & Human Services

HHS is the designated with the authority to administer the purchases for the Nation’s stockpile of bio-chem defense and pandemic vaccines and therapeutics. This session will provide a status report of their plans and activities for these purchases.

- What are the purchasing plans and priorities?
- What will be the length of contracts?
- How will guaranteed purchases be handled?
- What are the plans for replenishing the stockpile?
- Will contracts be tied solely to Bioshield funding?
- How is risk in development managed?

5:00 – 6:30

Networking Fair

In what has traditionally developed into a key part of the event, the *Bio-Chem Defense and Pandemic Vaccines and Therapeutic Networking Fair* provides the ideal opportunity for representatives from government, pharmaceutical and biotechnology companies, defense contractors, universities, schools of medicine and the public health community to come together to explore opportunities for partnering and collaboration.

Participating Government Agencies (to date):



FDA



USAMRMC/USAMRIID



DoD



DoC



NIH



HHS

April 26, 2006

Bio-chem Defense and Pandemic Vaccine and Therapeutic Legislation

Keynote Address:

8:00 – 9:00 THE HOUSE'S PLANS AND PRIORITIES FOR BIO-CHEM DEFENSE AND PANDEMIC VACCINE AND THERAPEUTIC LEGISLATION
The Honorable Curt Weldon, Representative (R-PA)

9:00 – 10:00 *Panel Discussion*
NEW LEGISLATION: WHAT IS NEEDED AND WHAT IS POSSIBLE

Moderator: **John Clerici**, *Partner*, McKenna Long & Aldridge LLP

Panelists:

Diane Berry, Ph.D., *Staff Director, Subcommittee on Prevention of Nuclear and Biological Attack, Committee on Homeland Security, U.S. House of Representatives*
Robert Kadlec, *Office of Senator Richard Burr, and Chairman of the Senate Subcommittee on Bioterrorism and Public Health Preparedness*
Wilson Wang, M.D., M.P.H., M.P.A., *Legislative Assistant, Health and Social Policy, Office of Senator Lieberman*

In order for the Nation to secure a long-term, sustainable supply of bio-chem defense and pandemic vaccines and therapeutics, Congress is working on new legislation to encourage and facilitate the development of a viable industry sector to meet the Nation's needs. The panelist will discuss the key issues that need to be addressed and how the legislation is approaching the issues.

- Expansion of Bioshield coverage
- Product procurement
- Rebates and grants
- Liability protection
- Patent provisions
- Accelerated approvals
- Biomedical Advanced Research Development Agency

10:00 – 10:30 *Morning Refreshment and Networking Break*

*Managing Priorities and Planning the Nation's Future Portfolio of Bio-chem
Defense and Pandemic Vaccines and Therapeutics*

10:30 – 12:00 Panel Discussion
APPLYING RISK BASED MANAGEMENT TECHNIQUES TO THE BIO-CHEM
DEFENSE PORTFOLIO
Moderator: **Bill Helming**, *Lead Partner, Biodefense and Public Health Practice,*
PRTM Management Consultants LLP

Panelists:

Michael J. Langford, DVM, Ph.D., *President, Emergent ImmunoSolutions*
Monique K. Mansoura, Ph.D., *Senior Planning Officer, Office of Research &
Development Coordination, Office of Public Health Emergency Preparedness,*
Department of Health and Human Services
Robin Robinson, Ph.D., *Senior Project Officer for Influenza, Department of Health
& Human Services*
Lota Zoth, *Chief Financial Officer, MedImmune*

An emerging technique for decision-making in major government programs is “risk-based management.” This panel will explore how such techniques might be applied to the challenges of managing the bio-chem defense R&D portfolio. Risks to be considered could include technology versus produce development, industry structure and dual sourcing, market assurance versus SNS management, suggested approach to portfolio management and governance, and measures of value. Panel participants will include both industry and government representatives.

12:00 Conference Adjourns