



# 7TH ANNUAL BIODEFENSE VACCINES & THERAPEUTICS

June 15-17, 2009 | Almas Temple Club | Washington DC

## Agenda

Tuesday, June 16, 2009

8:00-9:00

Morning Networking Breakfast sponsored by:



9:00 – 9:15

**Welcome and Introduction by the Conference Co-Chairs**

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

**Bill Helming**, *Vice President, Public Health and Biodefense Practice*, PRTM Management Consultants

9:15-10:00

**Coordinating Across Agencies and Integrating Missions**

The US Government is working to coordinate development of vaccines and therapeutics across multiple public health needs. To take advantage of this convergence of traditional biodefense with other public health investments, companies must offer technology innovations that can be broadly applied across sectors. Technology platforms, broad spectrum products, and flexible manufacturing innovations will reap rewards across sectors. Companies that align their portfolios to meet multiple public health funding streams will thrive in this new environment. This session will discuss the opportunities that this convergence in public health security offers.

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

**Bill Helming**, *Vice President, Public Health and Biodefense Practice*, PRTM Management Consultants

10:00-10:45

**BARDA and Opportunities for Biodefense Advanced Development and Acquisition**

The Biomedical Advanced Research and Development Authority (BARDA) is the lead agency in the Department of Health and Human Services that manages the advanced development and procurement of medical countermeasures for pandemic influenza, chemical, biological, radiological and nuclear (CBRN) threats, and

other emerging diseases. BARDA works to encourage industry participation in building the manufacturing infrastructure necessary for national preparedness. This presentation will detail BARDA's policy goals, progress and challenges, and strategies for building a vibrant emergency medical countermeasures sector.

- BARDA's priorities
- How to work with BARDA
- What biodefense and pandemic influenza products are currently in BARDA's advanced development and procurement portfolio?
- What is BARDA's timeline for new advanced development and procurement contracts?

**Gerald Kovacs, Ph.D.**, *Director, Division of CBRN Countermeasures, Biomedical Advanced Research and Development Authority, Office of Assistant Secretary of Preparedness and Response, Department of Health and Human Services*



10:45-11:15

Morning Networking break sponsored by:

11:15-12:00

**Biodefense Opportunities and Funding at the NIAID**

The National Institute of Allergy and Infectious Diseases (NIAID) is the key civilian government agency tasked with conducting early and mid-stage development of biodefense and pandemic influenza products. NIAID is also responsible for managing a number of high-containment labs used to study potentially lethal biological agents. This session will provide an update on NIAID's development priorities and funding opportunities, and its work in securing bioterror agents in high-containment labs.

- What are the current priorities for research and product development?
- What products are currently in NIAID's product portfolio?
- What products are NIAID actively seeking in FY2009?
- What is on the horizon for product needs in FY2009 and FY2010?
- What is the process for pursuing funding?
- What is the process for transferring from grant funding to contract funding?

**Michael Kurilla, M.D., Ph.D.**, *Director, Office of BioDefense Research Affairs and Associate Director for BioDefense Product Development, National Institute of Allergy and Infectious Diseases, NIH*

12:00-1:15

Group Luncheon

1:15-2:30

**Industry Panel: Working with HHS**

This panel of industry representatives will discuss their experience in working with the Department of Health and Human Services, highlighting their challenges and successes in working with HHS to develop and deliver necessary medical countermeasures.

Moderator:

**Jennifer Hanneschlager, Ph.D., MPH**, *Managing Director*, McKenna Long & Aldridge LLP

Panelists:

**James Davis, Ph.D., J.D.**, *Executive Vice President and General Counsel*, Human Genome Sciences, Inc.

**Neil Frazer, M.D.**, *Chief Medical Officer*, Chimerix, Inc.

**Alan Taggart**, *Vice President, Government Project Management*, MedImmune

**David Wright**, *President & CEO*, PharmAthene, Inc.

2:30-3:15

**Advanced Biodefense Research and Development Funding Opportunities at CBMS-JPMO**

The Chemical Biological Medical System Joint Project Management Office (CBMS-JPMO) at the Department of Defense (DoD) is responsible for research, development and acquisition of FDA approved medical countermeasures against chemical and biological threats.

- What are the current priorities for research, development and acquisition?
- What is the timeline for funding?
- What products are currently in the CBMS-JPMO portfolio?
- What is the process for working with CBMS?

**COL David Williams**, *Joint Project Manager, Chemical Biological Medical Systems*, Joint Program Executive Office for Chemical and Biological Defense

**Robert House, MSPH, Ph.D.**, *President*, DynPort Vaccine Company LLC, A CSC Company

3:15-3:45

**Biodefense Medical Research Opportunities and Funding at DTRA and TMTI**

The Defense Threat Reduction Agency (DTRA) at the Department of Defense (DoD) is tasked with providing strong medical defenses against chemical and biological weapons. To accomplish that mission, DTRA is pursuing early-stage development through the Transformational Medical Technologies Initiative (TMTI) and

through procurement of medical countermeasures. This presentation will provide an update on DTRA's development priorities and funding opportunities.

- What are the current priorities for product development under TMTI?
- What types of medical countermeasures is DTRA seeking?
- What is the funding timeline for these products?
- What are DTRA/TMTI's research priorities for FY2010 and FY2011?
- What is the process for pursuing funding and working with DTRA/TMTI?

**Randall Kincaid, Ph.D.**, *Scientific Director, TMTI Program*,  
Defense Threat Reduction Agency, Department of Defense

3:45-4:15 Afternoon Networking Break sponsored by: 

4:15-5:15 **Industry Panel: Working with DOD**  
This panel of industry representatives will discuss their experience working with the Department of Defense during the development of their biodefense products, the key challenges they faced, and their key success factors.

Moderator:


**Sean Jackson**, *Manager*, PRTM Management Consultants

Panelists:

**John Dong, M.D., Ph.D.**, *President & CSO*, GenPhar, Inc.

**Stan Goldman, Ph.D.**, *Director of Technology*, Evolva, Genetic Chemistry Inc.

**Robert House, MSPH, Ph.D.**, *President*, DynPort Vaccine Company LLC, A CSC Company

5:15 – 6:30 Reception sponsored by: 

Wednesday, June 17, 2009

8:00-9:00 Morning Networking Breakfast sponsored by: 

9:00-10:00 **Requirements: Setting the Market for Biodefense Products**  
The threats define the market space for health security products, but how do the threats get turned into a set of products that the government is seeking to procure to protect public health. This

session will explore the rationale and the process that the government follows to establish requirements for the products it seeks and move them into the stockpile.

Moderator:

**James Guyton**, *Principal, Public Health and Biodefense Practice, PRTM Management Consultants*

Panelists:

**Steve Adams, MPH**, *Deputy Director, Division of Strategic National Stockpile, Coordinating Center for Terrorism Preparedness and Emergency Response, Center for Disease Control and Prevention*

**Diane Berry, Ph.D.**, *Chief Scientist, Office of Health Affairs, Department of Homeland Security*

**Monique Mansoura, Ph.D.**, *Director for Policy, Planning and Requirements, Office of the Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services*



10:00-10:15

Morning Networking break sponsored by: **MedImmune**

10:15-11:15

### **The Global Approach to Funding for Health Security Medical Countermeasures**

As the call for biodefense vaccines and therapeutics extends into a more general call for Health Security, the industry enters an unprecedented time in history for potential funding available for research, development, procurement, and delivery of vaccines and biologics on a global scale. However, companies will need to think a bit differently about these opportunities, because many of these funders have philanthropic, economic development and/or social missions (rather than national security). Biopharmaceutical companies who position and act globally, and creatively think through their strategies to meet multiple missions, can possibly tap into multiple streams of funding.

Moderator:

**Robert Kadlec, M.D.**, *Vice President, Biodefense and Public Health Practice, PRTM Management Consultants*

Panelists:

**Carla Botting**, *Director, Commercial Affairs and Product Development, PATH Malaria Vaccine Initiative*

**Douglass Given, M.D., Ph.D., MBA, *Investment Partner, Bay City Capital***

**John Prakash, Ph.D., MBA, *Senior Vice President and Chief Scientific Officer, AMAR International, Inc.***

11:15-12:30

**Enablers for Medical Countermeasure Development and Production**

Developing and manufacturing vaccines and therapeutics is a difficult task in the best of circumstances. Developing products for Health Security is complicated by the hazardous materials required to make and test these products, and the unique facilities and infrastructure that support development and production. This session will explore strategies to create health security infrastructure including manufacturing facilities, animal rule study capacity, and the biosecurity measures required to protect the select agents.

Moderator:

**Matthew Veatch, *Senior Director, Public Health and Government Services, Global Corporate Development, Quintiles Transnational Corporation***

Panelists:

**Jeffrey Adamovicz, Ph.D., *Principal Science Advisor, Center for Biological Safety and Security, Mid-Atlantic Operations, Midwest Research Institute***

**Paula Bryant, Ph.D., *Senior S&T Manager, Chemical & Biological Technologies Directorate, Joint Science and Technology Office, Defense Threat Reduction Agency, Department of Defense***

**Alan Shaw, Ph.D., *President & CEO, VaxInnate Corporation***

**Brett Giroir, M.D., *Vice Chancellor for Research, The Texas A&M University System and Adjunct Professor, The Bush School of Government and Public Service***

**Thomas MacVittie, Ph.D., *Professor, Department of Radiation Oncology and Pathology, University of Maryland, School of Medicine, Baltimore***

12:30

Conference Adjourns

