



8TH ANNUAL BIODEFENSE VACCINES & THERAPEUTICS

June 14-17, 2010 | Almas Temple Club | Washington DC

Conference Agenda

Wednesday, June 16, 2010

8:00-9:00 Registration



8:00-9:00 Networking Breakfast hosted by

9:00 – 9:05 **Welcome and Opening Remarks**

John Clerici, *Principal*, Tiber Creek Partners, LLC
Chan Harjivan, *Director*, *Public Health and Biodefense Practice*,
PRTM Management Consultants, LLC

Rising to the Challenge

9:05-9:30 **Keynote Address**
George W. Korch Jr., Ph.D., *Senior Science Advisor, Office of the Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services*

9:30-10:30 **Panel Discussion: Future Direction for Combating Pandemic Flu and CBRN Threats**
This panel will review the government's response to the pandemic H1N1 influenza, including lessons learned, after action plan and the way forward for other looming public health emergencies such as the threat of CBRN agents.

Moderator:
Chan Harjivan, *Director, Public Health and Biodefense Practice*,
PRTM Management Consultants, LLC

Panelists:

Bruce Gellin, M.D., MPH, Deputy Assistant Secretary for Health and Director, National Vaccine Program Office, Department of Health and Human Services

Konrad Hayashi, M.D., MPH & TM, Chief Medical Officer, Epidemiology Surveillance and Response Branch (ESRB), Division of Bioterrorism Preparedness and Response (DBPR), National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), CCID, Center for Disease Control and Prevention

Erik Henschel, Ph.D., FAAM, Associate Director, Office of Vaccine Research & Review, Center for Biologics Evaluation & Research (CBER), U.S. Food and Drug Administration

Robin Robinson, Ph.D., Director, Biomedical Advanced Research and Development Authority (BARDA), Assistant Deputy Secretary, Office of Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services

10:30-11:00

Morning Networking break hosted by:



Opportunities and Funding

11:00-11:30

Presentation: 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. With an FY2010 budget increase requested for biodefense research, NIAID will explain potential changes to or impacts on its biodefense research program. This presentation will detail:

- NIAID's R&D focus
- Lessons learned from H5N1 and H1N1 experiences
- New R&D funding for biosecurity and emerging infectious diseases

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

11:30-12:00

Presentation: BARDA and Opportunities for Biodefense Advanced Development and Acquisitions

The Biomedical Advanced Research and Development Authority (BARDA) is the lead agency in the Department of Health and Human Services that manages the procurement of medical countermeasures for pandemic influenza, CBRN threats, and other emerging diseases. BARDA works to accelerate development of MCMs and building the manufacturing infrastructure necessary to respond rapidly to future pandemics and infectious threats. This presentation will detail:

- BARDA's funding, procurement and licensing strategies
- Lessons learned from H5N1 and H1N1 experiences
- New funding opportunities for building up the manufacturing infrastructure
- New R&D funding for biosecurity and emerging infectious diseases
- BARDA's R&D and procurement focus

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*

12:00-1:00

Group Luncheon

1:00-1:45

Industry Panel Discussion: 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:

John Clerici, *Principal, Tiber Creek Partners, LLC*

Panelists:

Daniel Abdun-Nabi, *President & COO, Emergent BioSolutions Inc.*

Paul Chaplin, Ph.D., *Executive Vice President, Research and Development & CSO, Bavarian Nordic, Inc.*

Theresa Dixon, M.B.A., M.S., *Vice President, Government Affairs & Health Economics, Advanced BioHealing, Inc.*

Matthew Duchars, *President, Genie Bio-Logic LLC*

Larry Zeitlin, Ph.D., *President, Mapp Biopharmaceutical, Inc.*

1:45-2:15

Joint Presentation: An Integrated Approach to Biodefense Medical Countermeasure Development and Acquisition

Presidential Directive and federal legislation have mandated better alignment and planning of the USG medical countermeasure (MCM) product development portfolio. BARDA has the mandate to develop MCMs for Chem, Bio, Rad, Nuc (CBRN) threats for civilians; DoD has the same mission for the Warfighter. This joint presentation will detail how these two agencies are coordinating their activities to accelerate products to licensure, including funding strategies and acquisition priorities.

John M. Hardham, Ph.D., *Commander, U.S. Navy, Deputy Medical Director, Office of the Deputy Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Programs (Chemical and Biological Defense), (OATSD (NCB/CB)), Department of Defense*

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*

2:15-3:15

Panel Discussion: An End-to-End Approach to Biodefense Medical Countermeasure Development and Acquisition

The development of vaccines and therapeutics is just one segment of the strategy to meet national preparedness and response objectives. Products that are developed must have a plan for production, supply and administration to accompany them. This session will present structures within the end-to-end preparedness framework responsible for setting requirements for stockpiling medical countermeasures.

Moderator:

Bill Helming, *Lead Partner, Biodefense and Public Health Practice, PRTM Management Consultants, LLC*

Panelists:

Steve Adams, MPH, *Deputy Director, Division of Strategic National Stockpile, Office of Public Health Preparedness and Response, Center for Disease Control and Prevention*

Susan Coller-Monarez, Ph.D., *Science Advisor, Chemical and Biological Division, Science and Technology Directorate, Department of Homeland Security*

Monique Mansoura, Ph.D., *Director for Medical Countermeasure 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



3:15-3:45

Afternoon Networking Break hosted by

3:45-4:15

Joint Presentation: Biodefense Medical Research Opportunities and Funding at DTRA and TMTI

The Medical Technologies Initiative (TMTI) is tasked with responding to the threat of emerging or intentionally bioengineered biology threats. The FY2010 budget requested increased funding for the Medical Biological Defense Program, which encompasses TMTI. This presentation will detail:

- TMTI's R&D priorities
- Types of medical countermeasures being sought
- Funding opportunities

Paula Bryant, Ph.D., *Chief, Medical S&T Division, Chemical & Biological Technologies Directorate, Joint Science and Technology Office, Defense Threat Reduction Agency, DOD*
Randall Kincaid, Ph.D., *Scientific Director, Transformational Medical Technologies Initiative (TMTI), Defense Threat Reduction Agency, DOD*

4:15-4:45

Presentation: 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. This presentation will detail:

- CBMS-JPMO's research, development and acquisition priorities
- Funding opportunities
- What products CBMS-JPMO is looking to procure for its portfolio?

LTC Philip Smith, Ph.D., *Joint Product Manager, Joint Vaccine Acquisition Program, Chemical Biological Medical Systems, Joint Program Executive Office for Chemical and Biological Defense, Department of Defense*

4:45-5:30

Industry Panel Discussion: 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:

George Dougherty, *Manager*, PRTM Management Consultants, LLC

Panelists:

Patrick Flavin, *Chief Legal Counsel*, Advanced Life Sciences Inc.

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

Patrick Iversen, Ph.D., *Senior Vice President of Strategic Alliances*, AVI BioPharma

Anne Radcliff, Ph.D., *Director, Biological & Medical Sciences*, CUBRC, Inc.

5:45 – 7:00

Reception sponsored by:



Thursday, June 17, 2010

8:00-9:00

Morning Networking Breakfast hosted by



9:00-9:45

Panel Discussion: Infrastructure Enablers for Medical Countermeasure Development

The development and production of Medical Countermeasure candidates in the USG portfolio requires unique capabilities and enabling infrastructure. The USG must find ways to meet the expanding demand for preclinical and advanced development testing & evaluation capability in support of Animal Rule regulatory requirements, as well as find reliable, flexible, and cost-effective advanced development and manufacturing models to produce medical countermeasures for which most are not commercially viable. The panel will discuss ongoing efforts and potential approaches to address these requirements.

Moderator:

Laura Smart, *Principal*, Tiber Creek Partners, LLC

Panelists:

Mark Dertzbaugh, Ph.D., *Chief, Business Plans & Programs*, USAMRIID

Judith Hewitt, Ph.D., *Chief, Biodefense Research Resources Section, Office of Biodefense Research Affairs, Division of*

Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), NIH
Jason Paragas, Ph.D., *Associate Director for Science, Office of the Chief Scientist, Division of Clinical Research*, National Institute of Allergy and Infectious Diseases (NIAID), NIH
Robin Robinson, Ph.D., *Director, Biomedical Advanced Research and Development Authority (BARDA), Assistant Deputy Secretary, Office of Assistant Secretary for Preparedness and Response (ASPR)*, Department of Health and Human Services
John Wade, DVM, Ph.D., *Vice President and Manager*, Battelle National Security Global Business



9:45-10:15

Morning Networking break hosted by

10:15-11:00

Panel Discussion: Enabling Technologies for Medical Countermeasures

There are many technologies in development, while not medical countermeasures in the traditional sense, which support the overall mission of public health preparedness. This panel will discuss novel production capabilities, adjunct therapies, and in silico drug discovery technologies and how these approaches to drug and vaccine development enable the medical countermeasure enterprise.

Moderator:

Jennifer Hanneschlager, *Principal*, Tiber Creek Partners, LLC

Panelists:

Nigel Duffy, Ph.D., *CTO*, Numerate, Inc.

Rebecca Osborne, *Senior Manager – Operations and Project Management*, Implicit Bioscience Ltd.

Lesley Stolz, Ph.D., *Vice President of Business Development*, Sutro BioPharma, Inc.

11:00-11:45

Panel Discussion: Business Models for Countermeasure Development

Limited commercial market potential, unique requirements and inherent risks associated with biodefense Medical Countermeasures present both large and small pharmaceutical developers with barriers to engagement in MCM development. By applying a mix of market incentives and risk mitigation strategies, the USG can engage experienced manufacturers to develop medical countermeasures individually or through effective partnerships. The panel will explore potential strategies and business models that may be applied to address these challenges.

Moderator:

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

Panelists:

David Marks, Esq., *Senior Commercialization Officer*, PATH

George Painter, Ph.D., *Chairman of the Board and CSO*,
Chimerix, Inc.

Brad Smith, Ph.D., *Senior Associate*, Center for Biosecurity of
UPMC

11:45

Conference Adjourns