

Biomedical Advanced Research and  
Development Authority (BARDA)

Industry Day

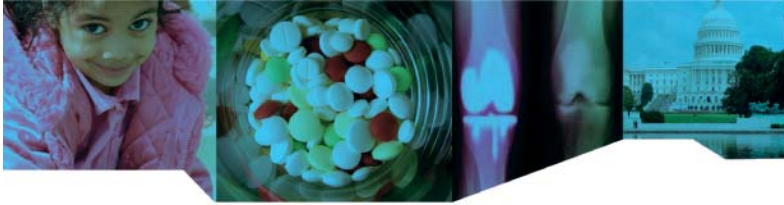


U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Preparedness and Response

# **Biomedical Advanced Research and Development Authority (BARDA)**

## **INDUSTRY DAY**

*August 3, 2007  
The Fairmont Hotel Washington  
Washington, DC*

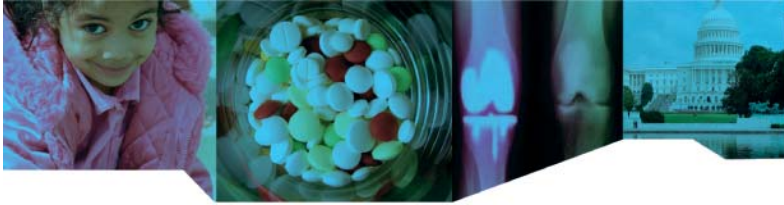


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Reston, VA 20191



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## EXECUTIVE SUMMARY

The Office of Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), an operating division of the Department of Health and Human Services (HHS), is responsible for providing coordination and expert advice regarding late-stage advanced development and procurement of public health emergency medical countermeasures. Through the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), BARDA supports ASPR in coordinating interagency efforts to define and prioritize requirements for public health emergency medical countermeasures; to carry out related research and product development; and to ensure medical countermeasures acquired by HHS are available and can be effectively utilized in an emergency. In support of this mission and to support HHS objectives to be both a steward of the public's trust and a reliable partner with private industry, BARDA hosted its inaugural Industry Day on Friday, August 3, 2007 at the Fairmont Hotel Washington in Washington, DC.

For those companies interested in developing medical countermeasures relevant to the priorities outlined in either the *HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats* or the *HHS Pandemic Influenza Implementation Plan*, the 2007 BARDA Industry Day provided an opportunity to present biodefense and public health countermeasure technologies in vaccines, therapeutics, and medical diagnostics. Industry Day was a public meeting open to industry, academia, international agencies, and representatives from various federal government agencies. In total, more than 300 attendees participated in the 2007 BARDA Industry Day. The list of organizations participating in Industry Day is provided in Appendix I.

The 2007 BARDA Industry Day included four concurrent sessions during which industry stakeholders presented product information:

- Vaccines
- Therapeutics
- Influenza and Non-Pharmaceutical Countermeasures
- Countermeasures for Nuclear, Radiological, Chemical Threats and Diagnostics.



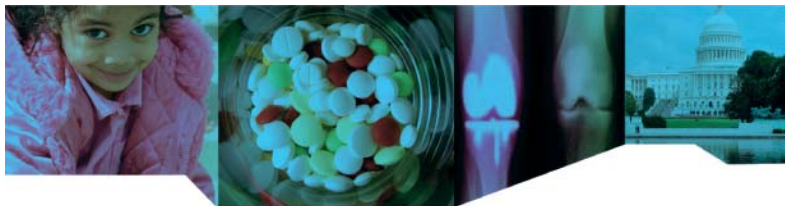
## FOR MORE INFORMATION

To find out more about BARDA Industry Day, please visit the BARDA Web site at <http://www.hhs.gov/disasters/press/newsroom/spotlight/2007bardaday.html>. This Web site provides a wide range of information on Industry Day, including the agenda, list of attendees, and links to the *HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats* and the *HHS Pandemic Influenza Implementation Plan*.

The Office of Biomedical Advanced Research and Development Authority in the Office of the Assistant Secretary for Preparedness and Response can be reached by telephone at 202-260-1200; by fax at 202-205-4520; and by e-mail at [BARDA@hhs.gov](mailto:BARDA@hhs.gov).

## UPCOMING EVENTS

The HHS Public Health Emergency Medical Countermeasure (PHEMC) Enterprise Stakeholders Workshop occurs annually. Future Enterprise Stakeholders Workshops will include industry presentations, such as those conducted during the 2007 BARDA Industry Day. The date of the next PHEMC Enterprise Stakeholders Workshop is currently being determined. As scheduling and registration information becomes available, it will be posted on the BARDA Website at <http://www.hhs.gov/aspr/barda>.



## APPENDIX I

### 2007 BARDA INDUSTRY DAY ATTENDANCE

#### Summary:

Industry	217
Federal Government	37
Other	32
Academia	8
Healthcare Provider/First Responder	7
Media	2
State/Local/Tribal Government	<u>1</u>
<b>Total</b>	<b>304</b>

#### Organizations/Agencies

20/20 BioResponse	BCM Group, LLC
Acambis, Inc.	BD Technologies
Accutera, Inc.	Becton, Dickinson and Company
Achaogen, Inc.	BioFactura, Inc.
ADButler & Associates, Inc.	BioPharm Services, Inc.
Advanced Liquid Logic, Inc.	Biosome, Inc.
Agilent Technologies	Booz Allen Hamilton, Inc.
Air Innovations	British Embassy, UKTI
Alliance for Biosecurity	Buchanan Ingersoll & Rooney
ALung Technologies, Inc.	Cellerant Therapeutics, Inc.
Amax, Ltd.	Center for Biosecurity of the University of Pittsburgh Medical Center
American Type Culture Collection (ATCC)	Cepheid
Apro Bio Pharmaceutical Corporation	Civitas Group, LLC
Arnold & Porter, LLP	Cleveland BioLabs, Inc.
Aspera Biosystems, Inc.	College of American Pathologists
Aton Pharma, Inc.	CombiMatrix Corporation
Avecia Biologics, Ltd.	Computer Sciences Corporation (CSC)
Bacilligen, Inc.	Comtech Mobile Datacom Corporation
BAE Systems, Inc.	Countervail Corporation
BAI, Inc.	CSC North American Public Sector
Battelle National Biodefense Institute	CytoGenix, Inc.
Bavarian Nordic, Inc.	Diagnostic Hybrids, Inc
Baxter BioScience Corporation	DomesticPreparedness.com
Baxter Healthcare Corporation	DOR BioPharma, Inc.
Bayer HealthCare Pharmaceuticals	Dowpharma
Bayside Materials Technology	



Dynavax Technologies Corporation  
DynPort Vaccine Company, LLC, a CSC  
Company

EBI

Eli Lilly and Company

Emergent BioSolutions

Emergent Technologies, Inc.

Emisphere Technologies, Inc.

ENSCO, Inc.

Epitopix, LLC

European Commission Delegation

E-Z-EM, Inc.

Fabiani & Company

Fast-Track Drugs & Biologics, LLC

Federal Drug Agency

Flu Wiki

Functional Genetics, Inc.

Genocea Biosciences

GenPhar, Inc.

Global Protection

GlobelImmune, Inc.

GMD BIO ADVANCE, Inc.

Harvard Medical School

Heyltech Corp.

Humabs, LLC

Humanetics

Hyman, Phelps & McNamara, PC

Ichor Medical Systems, Inc.

ICx Biosystems

Imigene, Inc.

ImmuneRegen BioSciences, Inc.

ImmunoBiology, Ltd.

Implicit Bioscience, Inc.

Innovative Biologics, Inc.

Integrated Warehousing Solutions, LLC

Iomai Corporation

J. Craig Venter Institute

Johns Hopkins University

Juvaris BioTherapeutics, Inc.

Kaketsuken

Kleiner Perkins Caufield & Byers

Klitenic Robertson, PLLC

Logical Images, Inc.

Lovelace Respiratory Research Institute

McKenna Long & Aldridge, LLP

Meridian Medical Technologies, Inc.

MITRE Corporation

Molecular Express, Inc.

Mystic Pharmaceuticals, Inc.

Nanotherapeutics, Inc.

NanoViricides, Inc.

National Security Health Policy Center

*New York Times*

New York University - CCPR

NexBio, Inc.

Noninvasive Medical Technologies

Northrop Grumman Corporation

Norwood Immunology, Limited

Oncovir, Inc.

Orchestra Therapeutics, Inc.

Osiris Therapeutics, Inc.

PanThera Biopharma, LLC

PAREXEL MedCom

Patton Boggs, LLP

Pfizer, Inc.

PharmAthene, Inc.

Planet Biotechnology, Inc.

Policy Directions, Inc.

PolyMedix, Inc.

PRTM Management Consultants

Quintiles Public Health & Government Services

Quintiles Public Health Development

Quintiles Transnational Corp.

R W Potter

Radix BioSolutions

Receptor Logic, Ltd.

Robinson Consulting

RTI International

RxBio, Inc.

SAFC Pharma

Science Applications International Corporation  
(SAIC)

Sanochemia Pharmazeutika AG

Sanochemia Corp.

sanofi pasteur

Sarnoff Corporation

Scian Institute

SIGA Technologies, Inc.

Southern Research Institute

Southwest Research Institute

Spaltudaq Corporation

SRI International



State of Maryland  
Stormbio, Inc.  
Sun Microsystems, Inc.  
Symphogen A/S  
Syntiron, LLC  
Tetracore, Inc.  
The Chancellor Group  
The Federal Market Group, Ltd.  
The Housman Group  
The JF Group  
The MITRE Corporation  
TioxoClean, Inc.  
University of Maryland School of Medicine  
University of Rochester Medical Center  
University of Texas Medical Branch  
U.S. Department of Commerce  
    Bureau of Industry and Security  
U.S. Department of Defense  
    Armed Forces Institute of Pathology  
    Army Medical Research Institute of Infectious  
        Diseases  
    Office of Naval Research  
U.S. Department of Health and Human Services  
    Centers for Disease Control and Prevention  
    Food and Drug Administration

National Institutes of Health  
Office of the Assistant Secretary for  
    Preparedness and Response  
Office of the Inspector General  
U.S. Department of Homeland Security  
    Office of Health Affairs  
U.S. Government Accountability Office  
U.S. Library of Congress  
    Congressional Research Service  
U.S. Senate  
    Homeland Security and Governmental Affairs  
        Committee  
    Office of Senator Richard Burr  
Valeant Pharmaceuticals International  
VaxDesign Corporation  
VaxInnate Corporation  
VIASYS Respiratory Care, Inc.  
Vical Incorporated  
VIGILAIR Systems, Inc.  
Vironova AB  
WBB Securities, LLC  
West Coast Biologicals  
Yale New Haven Center for Emergency  
    Preparedness and Disaster Response





## APPENDIX II

### 2007 BARDA INDUSTRY DAY AGENDA

<b>VACCINES</b>			
<b>Welcome:</b>	<b>Michael Balady, PhD, MSPH</b> – <i>Acting Director of Acquisitions Management Systems, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>		
<b>Moderator:</b>	<b>Gerald R. Kovacs, PhD</b> – <i>Acting Director of Project BioShield -Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>		
<b>Time</b>	<b>Presenter</b>	<b>Company</b>	<b>Title</b>
8:00	Gary Nabors, PhD Michael Langford, DVM, PhD	Emergent BioSolutions, Inc.	Enhancements to the FDA Approved Anthrax Vaccine: BioThrax®
8:30	John Y. Dong, MD, PhD	GenPhar, Inc.	Multivalent Filovirus Vaccine Protects Nonhuman Primates against Multi-Strain, Lethal Ebola and Marburg Virus Infections
9:00	Kimber Poffenberger, PhD Mervyn Hamer, BS	Iomai Corporation	Transcutaneous Immunization (TCI): A Platform Technology for Biodefense Vaccines
9:30	John Mikszta, PhD Vincent J. Sullivan	Becton, Dickinson & Company (BD)	Microneedle-Based Intradermal Delivery of Protein Biodefense Vaccines
10:00	Brian Livingston, PhD	Dynavax Technologies	Application of Immunostimulatory DNA Adjuvants for Anthrax and Pandemic Influenza Vaccines
10:30	Chris Bailey, PhD	ImmunoBiology, Ltd	The Application of Heat Shock Protein Complexes (HspCTM) Against Emergent Pathogens, Demonstrated with TB
11:00	John Mikszta, PhD Vincent J. Sullivan	Becton, Dickinson & Company (BD)	A Stable, Intranasal (IN) Dry Powder Anthrax Vaccine based on Recombinant Protective Antigen (rPA)
<b><i>Lunch 11:30 – 1:00</i></b>			
1:00	Alain Luxembourg, MD, PhD	Ichor Medical Systems	Electroporation Based Delivery Platform To Enhance DNA Immunization
1:30	Lisa Herron-Olson, PhD R.H. Joseph Shaw	Syntiron™, Inc.	Iron-regulated Bacterial Surface Proteins as Broadly Protective Vaccines
2:00	Kent R. Van Kampen, DVM, PhD	Vaxin, Inc.	Non-Replicating Adenovirus-Vectored Intranasal Anthrax Vaccine
2:30	Alexander Grinberg, MD	GMD BIO Advance, Inc.	Encapsulation Technology to Stabilize and Deliver Vaccines



## THERAPEUTICS

<b>Welcome:</b>	<b>Jerome A. Donlon, MD, PhD</b> - <i>Chief Scientist, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>		
<b>Moderator:</b>	<b>Matthew Lawlor, PhD</b> - <i>Program Analyst, Presidential Management Fellow, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>		
<b><u>Time</u></b>	<b><u>Presenter</u></b>	<b><u>Company</u></b>	<b><u>Title</u></b>
8:00	David W. Moskowitz, MD, FACP	GenoMed, Inc.	A General Viral Antidote?
8:30	Michael Goldblatt, PhD, JD	Functional Genetics, Inc.	A New Paradigm: Host Oriented Therapeutics for Infectious Disease
9:00	Andres M. Salazar, MD	Oncovir, Inc.	Nasal Hiltonol® (Poly-ICLC) and Liposomal-Encased Hiltonol® Prophylaxis and Treatment of Pandemic Influenza Infection, SARS and other Respiratory Threats: Broad Spectrum Activation of Mucosal Innate and Adaptive Immunity (TRL-7)
9:30	John Cheronis, MD, PhD	Accutera, Inc.	Serine Elastase Inhibitors for Treatment and Post-Exposure Prophylaxis of Patients Exposed to Category A Pathogens
10:00	Gary Nabors, PhD	Emergent BioSolutions, Inc.	Development of a Human Anthrax Immune Globulin Intravenous (AIGIV) Therapeutic Agent for Treatment of Anthrax Disease
10:30	Hal Siegel, PhD	ImmuneRegen Biosciences, Inc.	Homspera™ Shows Efficacy at Mitigating the Effects of Gamma Radiation and Biological Insults
11:00	Anil R. Diwan, PhD	NanoViricides, Inc.	Broad-spectrum Targeted Antiviral Nanomedicines
11:30	Keith Wycoff, PhD Elliott Fineman, MS, JD	Planet Biotechnology, Inc.	Development of an Immunoadhesin Therapy for Inhalational Anthrax
<b><i>Lunch 11:30 – 1:00</i></b>			



## THERAPEUTICS, *continued*

1:00	Luis Branco	BioFactura, Inc.	Fully Human Monoclonal Antibodies as Countermeasures to Smallpox
1:30	Richard F Rest, PhD	Drexel University College of Medicine	STIMAL (Liposome-Encapsulated N-Acetylcysteine) Increases the Ability of Human Macrophages to Kill <i>Bacillus anthracis</i>
2:00	Alexander Grinberg, MD Vladimir Karginov, PhD	GMD BIO Advance, Inc.	Anti-Adhesion Blockers of Infection
2:30	George Jiang, PhD	CEL-SCI, Corp.	Phenotypic and functional characterization of liver lymphocytes from CEL-1000-treated A/J mice protected against malaria sporozoite challenge
3:00	Wendy Painter, MD	Chimerix Inc.	Development of CMX001, an Antiviral Agent for the Prophylaxis and Treatment of Smallpox
3:30	Alan Wolfman, PhD	Cleveland BioLabs, Inc.	CBLB502, a Radiation Medical Countermeasure that Targets Both the GI and HP Systems.
4:00	Professor Richard Boyd, PhD	Norwood Immunology	Rejuvenation of the Thymus and Bone Marrow as a Fundamental Platform for Enhancing Immune Recovery Following Bio-terrorism



## INFLUENZA AND NON-PHARMACEUTICAL COUNTERMEASURES

<b>Welcome:</b>	<b>Robin Robinson, PhD</b> , <i>Director of Pandemic Influenza and Emerging Infection Programs, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>		
<b>Moderators:</b>	<p><b>George Robertson, PhD</b>, <i>Senior Program Manager - K.W. Tunnell (contractor) supporting the mission of: Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i></p> <p><b>William J. Kramp PhD</b>, <i>Diagnostics Project Manager (Pandemic Influenza) - K.W. Tunnell (contractor) supporting the mission of: Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i></p>		
<b>Time</b>	<b>Presenter</b>	<b>Company</b>	<b>Title</b>
8:00	John Mikszta, PhD Vincent J. Sullivan	Becton, Dickinson & Company (BD)	Microneedle-Based Intradermal Delivery of Protein Biodefense Vaccines
8:30	Alex Franzusoff, PhD	GlobeImmune, Inc.	Clinical and Preclinical Evidence for Potent Immune Activation with the Tarmogen™ Vaccine Platform
9:00	Ashley Birkett PhD	Acambis, Inc.	Universal Influenza A Vaccine Candidate
9:30	Alan Shaw, PhD	VaxInnate Corporation	Expression of Recombinant Flagellin Fusion Proteins Yields Potent Vaccines Against Influenza and Other Infectious Diseases, an Efficient National Solution (M2e).
10:00	Peggy Lalor, PhD	Vical Incorporated	Plasmid DNA Vaccination with Conserved Influenza Antigens Protects against Viral Challenge
10:30	Chris Bailey, PhD	ImmunoBiology Ltd,	The Application of ImmunBodies™ Technology Against Emergent Pathogens, Demonstrated with Influenza
11:00	Jeff Fairman, PhD	Juvaris BioTherapeutics, Inc.	Adjuvanting of existing flu vaccines with Cationic Lipid-DNA complexes (JuvaVax™) for cross-protection and dose-sparing
11:30	Gary Fujii, PhD	Molecular Express, Inc.	M2-based Pandemic Influenza Vaccine
<b><i>Lunch 12:00 – 1:00</i></b>			



## INFLUENZA AND NON-PHARMACEUTICAL COUNTERMEASURES, *continued*

1:00	Alan Shaw, PhD	VaxInnate Corporation	Expression of Recombinant Flagellin Fusion Proteins Yields Potent Vaccines Against Influenza and Other Infectious Diseases, an Efficient National Solution (HA).
1:30	David Wurtman, MD, MBA	NexBio, Inc.	Development of Fludase® as a Broad-Spectrum Therapeutic Agent for Seasonal and Pandemic Influenza
2:00	Pamela Jackson	SeQual Technologies Inc.	Innovative Eclipse Portable Oxygen System for Point of Use Medical Applications during Mission Critical Pandemics and All-Hazards Preparedness
2:30	Michael L. Wetzell, PE	Air Innovations	Portable Isolation Unit
3:00	Gary Fujii, PhD	Molecular Express, Inc.	Regeneration Therapy
3:30	William Warren, PhD	VaxDesign Corporation	Modular Immune <i>In Vitro</i> Constructs (MIMIC) For Rapid Vaccine Assessment
4:00	Ann McCaughan BSN, RN, PhD Catherine DeMarr	Noninvasive Medical Technologies, Inc.	A Noncontact Cardiopulmonary and Diagnostic Tool
4:30	Brooke McCutchan, MT Jimmy Page, PhD	Diagnostic HYBRIDS	Automated Cell Interrogation System
5:00	Louis J. Cantolupo, BS, MBA	GenVec, Inc.	Proprietary Human Cell Platform for Therapeutic/Vaccine Development



## NUCLEAR, RADIOLOGICAL, CHEMICAL AND DIAGNOSTICS

<b>Welcome:</b>	<b>Monique K. Mansoura, PhD</b> , <i>Acting Deputy Director - Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>		
<b>Moderators:</b>	<b>Ronald Manning, PhD</b> , <i>Project Officer - Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>  <b>Roxanne Shively, MS</b> , <i>Project Officer - Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services</i>		
<b>Time</b>	<b>Presenter</b>	<b>Company</b>	<b>Title</b>
8:00	Barry Levinson, PhD	Aton Pharma, Inc.	Use of Syprine® and Cuprimine®, FDA-approved Therapeutics for Wilson Disease, as Oral Radioisotope Decorporation Agents
8:30	C. Randal Mills, PhD	Osiris Therapeutics, Inc.	Use of Adult Mesenchymal Stem Cells as a Therapeutic Countermeasure
9:00	Zsolt Harsanyi, PhD Richard M Carlton, MD	Exponential Biotherapies, Inc.	A Peptide that Significantly Protects Mice from the Lethal Effects of Radiation Even When Administered 3 Days Post-Exposure, and is Well Tolerated in Man
9:30	Joseph Albanese, PhD Elaine Forte, BS, MT	Yale New Haven Center for Emergency Preparedness and Disaster Response	An Approach towards Building Connecticut's Clinical Biodosimetry Laboratory Surge Capacity to Mitigate the Health Consequences of Radiological and Nuclear Disasters
10:00	Edson X. Albuquerque, MD, PhD	Countervail Corporation	Galantamine: A Novel Medical Countermeasure Against Organophosphorus Poisoning
10:30	W. Shannon McCool, DPh Gabor Tigyí, MD, PhD	RxBio, Inc.	RX100 - A Novel Radioprotectant & Radiomitigator
11:00	Romy Nocera, PhD Tom Holder	Valeant Pharmaceuticals International	Readiness for Nerve Agent and Chemical Attacks: Rectal Diazepam in Seizure Emergencies
11:30	Milton Smith, MD	Amaox. Ltd.	The use of STIMAL as countermeasure to mustard gas and potentially other chemical weapons
<b><i>Lunch 11:30 – 1:00</i></b>			



## NUCLEAR, RADIOLOGICAL, CHEMICAL AND DIAGNOSTICS, *continued*

1:00	William Goodwin, BS, MS	Cepheid	Rapid, Point-of-Care Diagnostics Using the GeneXpert® in Response to a Bioterrorism Event
1:30	Richard West	Advanced Liquid Logic, Inc.	Platform Diagnostic Analyzer for Chem & Bio Threats
2:00	Charles Saller, PhD	Biosome, Inc.	Rapid Selection of Treatment for Bacterial Pathogens
2:30	Jon Weidanz, PhD	Receptor Logic, Ltd.	Disease Monitoring through Detection of Specific Peptide-HLA Complexes
3:00	Mohammed Homman	Vironova AB	Virus Detection and Diagnostics by Automated Digital Image Analysis
3:30	Michel Agadjanyan, PhD	GM.D. BIO Advance, Inc.	Generation of Single Platform Diagnostic Test for Category A and B Pathogens
4:00	Raymond Akers, PhD	Akers Biosciences, Inc.	Multi-Platform, Rapid, Point-of Care Bio-Assay
4:30	Keith Crawford, MD, PhD	Harvard Medical School/ Brigham and Woman's Hospital	<i>B. anthracis</i> - and <i>Y. pestis</i> -Specific Gene Expression in Antigen Presenting Cells
5:00	Gary Fujii, PhD	Molecular Express, Inc.	Viratrodes