Agenda – Day One – July 31, 2007

**Opening Session**

8:00 – 8:25am

**WELCOME AND OPENING SESSION**

Carol D. Linden, Ph.D.
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

RADM W. Craig Vanderwagen, M.D.
Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Secretary Michael O. Leavitt
U.S. Department of Health and Human Services

8:25 – 8:45am

**PANDEMIC AND ALL-HAZARDS PREPAREDNESS**

RADM W. Craig Vanderwagen, M.D.
Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

8:45 – 9:00am

**BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) IMPLEMENTATION**

Carol D. Linden, Ph.D.
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

9:00 – 9:15am

**NATIONAL STRATEGY FOR MEDICAL COUNTERMEASURES AGAINST WEAPONS OF MASS DESTRUCTION**

Rajeev Venkayya, M.D.
Special Assistant to the President for Biodefense, Homeland Security Council, Executive Office of the President

9:15 – 9:30am

**NATIONAL INSTITUTES OF HEALTH’S CBRN MEDICAL COUNTERMEASURE ACTIVITIES**

Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infectious Diseases
National Institutes of Health, U.S. Department of Health and Human Services

9:30 – 9:45am

**CENTERS FOR DISEASE CONTROL AND PREVENTION’S CBRN MEDICAL COUNTERMEASURE ACTIVITIES**

Greg Burel
Acting Director, Division of Strategic National Stockpile
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

9:45 – 10:00am

**FOOD AND DRUG ADMINISTRATION’S CBRN MEDICAL COUNTERMEASURE ACTIVITIES**

Andrew C. von Eschenbach, M.D.
Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services

10:00 – 10:15am

**DEPARTMENT OF HOMELAND SECURITY ADDRESS**

Jeff Runge, M.D.
Acting Assistant Secretary for Health Affairs
Chief Medical Officer, U.S. Department of Homeland Security

10:15 – 10:30am

**DEPARTMENT OF DEFENSE, CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM:**

CBRN MEDICAL COUNTERMEASURES PROGRAM

Jean D. Reed
Special Assistant to the Secretary of Defense for Chemical Biological Defense and Chemical Demilitarization Programs, U.S. Department of Defense
Break 10:30 - 10:50

Panel Session I

HHS CBRN Medical Countermeasure Preparedness Efforts – Stakeholder Response

10:50 – 11:10am

**INDUSTRY PANEL**

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

*Chris Colwell*
Director, Healthcare Regulatory Affairs, Biotechnology Industry Organization (BIO)

*Del Persinger*
Senior Vice President and Chief Financial Officer, Pharmaceutical Research and Manufacturers of America

11:15 – 11:35am

**ACADEMIA/ SCIENCE PANEL**

*Moderator: Carol D. Linden, Ph.D.*
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

*Tara O'Toole, M.D., M.P.H.*
Chief Executive Officer and Director, Center for Biosecurity of the University of Pittsburgh Medical Center

*Deborah Anderson, Ph.D.*
Associate Director, Regional Biocontainment Laboratory
Department of Veterinary Pathobiology, University of Missouri

*Paul Okunieff, M.D.*
Center for Medical Countermeasures Against Radiation Steering Committee Chair
CBARMFI (Rochester) Principal Investigator

11:40 – 12:00pm

**MEDICINE AND PUBLIC HEALTH PANEL**

*Moderator: Gerald W. Parker, D.V.M., Ph.D., M.S.*
Principal Deputy Assistant Secretary
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

*James J. James, M.D., Dr.P.H., M.H.A.*
Director, Center for Public Health Preparedness and Disaster Response, American Medical Association

*Nancy L. Hughes, M.S., R.N.*
Director, Center for Occupational and Environmental Health, American Nurses Association

*Georges C. Benjamin, M.D.*
Executive Director, American Public Health Association

12:05 – 12:25pm

**STATE, LOCAL, AND TRIBAL RESPONSE PANEL**

*Moderator: Kevin Yeskey, M.D.*
Deputy Assistant Secretary and Director, Office of Preparedness and Emergency Operations
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

*James S. Blumenstock, M.A.*
Chief Program Officer, Public Health Practice, Association of State and Territorial Health Officials

*Jack Hermann*
Project Director for Public Health Preparedness, National Association of County and City Health Officials

*Robert Holden*
Director, Emergency Management and Radioactive Waste Programs, National Congress of American Indians

Lunch 12:30 - 2:00
### Agenda – Day One – July 31, 2007

#### SEUMTANEOUS WORK SESSIONS

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| 2:00 – 3:30pm | **SEMINAR SESSION I**  
**Contracting with HHS for Medical Countermeasure Development and Acquisition**  
**Implementation**  
Groups A1, A2, and A3  
**Federal Partnership with State, Local, and Tribal Authorities in Preparedness and Response**  
Groups B1 and B2  
**Incentivizing Private Industry to Support CBRN Medical Countermeasure Preparedness**  
Groups C1 and C2  
**Medical Countermeasure Concept of Operations: Making the Connection between Development and End User Utility**  
Group D1  
**Technological Innovations to Improve Medical Countermeasure Response and to Meet the Challenge of Novel and Emerging Threats**  
Group E1 |
| 3:30 – 3:50pm | **BREAK**  
3:30 – 3:50pm | **OPENING**  
RoseMary Mann  
Contracting Officer, Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services |
| 3:55 – 4:25pm | **FEDERAL ACQUISITION REQUIREMENTS (FAR) 101 AND BARDA CONTRACTING**  
Brian Goodger, M.S.  
Contracting Officer, Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services |
| 4:25 – 4:40pm | **NATIONAL INSTITUTES OF HEALTH RESEARCH AND DEVELOPMENT ACQUISITION PROCESSES**  
Charles Grewe  
Director, Office of Acquisitions, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases  
National Institutes of Health, U.S. Department of Health and Human Services |
| 4:40 – 4:55pm | **CENFRS FOR DISEASE CONTROL AND PREVENTION, DIVISION OF THE STRATEGIC NATIONAL STOCKPILE ACQUISITION PROCESSES**  
Steven A. Adams, M.P.H.  
Deputy Director, Division of Strategic National Stockpile  
Coordinating Office for Terrorism Preparedness and Emergency Response  
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services |
| 4:55 – 5:10pm | **MEDICALCOUNTERMEASURES.GOV (A STAKEHOLDER PORTAL)**  
Matthew Lawlor, Ph.D.  
Program Analyst, Presidential Management Fellow  
Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services |
<p>| 5:10 – 5:30pm | <strong>Q AND A</strong> |
| <strong>NETWORKING SOCIAL</strong>  | 5:30 - 7:00 |</p>
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<tr>
<td>8:00 – 8:10am</td>
<td><strong>WELCOME</strong></td>
<td>Carol D. Linden, Ph.D.</td>
<td>Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority</td>
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<td>8:10 – 8:30am</td>
<td><strong>NATIONAL PANDEMIC INFLUENZA PLAN</strong></td>
<td>Kenneth Staley, M.D., M.P.A.</td>
<td>Director for Biodefense Policy, Homeland Security Council, Executive Office of the President</td>
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<td>8:30 – 8:45am</td>
<td><strong>HHS PANDEMIC INFLUENZA IMPLEMENTATION PLAN – PROGRESS TO DATE</strong></td>
<td>ADM John O. Agwunobi, M.D., M.B.A., M.P.H.</td>
<td>Assistant Secretary for Health, U.S. Department of Health and Human Services</td>
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<td>8:45 – 9:00am</td>
<td><strong>NATIONAL VACCINE PROGRAM OFFICE’S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES</strong></td>
<td>Bruce Gellin, M.D., M.P.H.</td>
<td>Director, National Vaccine Program Office</td>
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<td>Office of Public Health and Science, U.S. Department of Health and Human Services</td>
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<td>9:00 – 9:15am</td>
<td><strong>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE IMPLEMENTATION ACTIVITIES</strong></td>
<td>Gerald W. Parker, D.V.M., M.B.A., Ph.D., M.S.</td>
<td>Principal Deputy Assistant Secretary</td>
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<td>9:15 – 9:30am</td>
<td><strong>NATIONAL INSTITUTES OF HEALTH’S PANDEMIC INFLUENZA IMPLEMENTATION ACTIVITIES</strong></td>
<td>Roland A. Levandowski, M.D.</td>
<td>Chief, Influenza, SARS and Other Viral Respiratory Diseases Section, Respiratory Diseases Branch</td>
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<td>Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases</td>
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<td>National Institutes of Health, U.S. Department of Health and Human Services</td>
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<td>9:30 – 9:45am</td>
<td><strong>CENTERS FOR DISEASE CONTROL AND PREVENTION’S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES</strong></td>
<td>CAPT Stephen C. Redd, M.D.</td>
<td>Director, Influenza Coordination Unit</td>
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<td>Centers for Disease Control and Prevention, U.S. Department of Health and Human Services</td>
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<td>9:45 – 10:00am</td>
<td><strong>FOOD AND DRUG ADMINISTRATION’S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES</strong></td>
<td>Mark Goldberger, M.D., M.P.H.</td>
<td>Medical Director for Emerging and Pandemic Threat Preparedness, Center for Biologics Evaluation and Research</td>
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<td>Food and Drug Administration, U.S. Department of Health and Human Services</td>
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<td>10:00 – 10:15am</td>
<td><strong>DEPARTMENT OF DEFENSE PANDEMIC INFLUENZA ACTIVITIES</strong></td>
<td>LTC Wayne E. Hache, D.O., M.P.H.</td>
<td>Director Preventive Medicine, Office of the Assistant Secretary of Defense (Health Affairs)</td>
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<td>Force Health Protection and Readiness, U.S. Department of Defense</td>
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PLENARY SESSION III
CBRN and Pandemic Influenza: Threats and Medical/Public Health Consequences

10:35 – 11:15am
**PANDEMIC INFLUENZA ANTIVIRAL DRUG STOCKPILE PARTNERING PANEL**

*Moderator: Arthur Y. Elliot, M.D., Ph.D.*
Senior Program Manager, Antivirals, Pandemic Influenza Preparedness
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

*Dominick Iacuzio, Ph.D.*
Medical Director, Hoffman-La Roche, Inc.

*Adam Kesselman*
Relenza Global Product Director, GlaxoSmithKline

*Susan C. Penfield, M.D.*
Manager, Infectious Disease Control Unit, Texas State Department of Health

*Stephen S. Morse, Ph.D., F.A.A.M., F.A.C.E.*
Founding Director & Senior Research Scientist, Center for Public Health Preparedness
National Center for Disaster Preparedness: Assoc. Professor, Columbia University, Mailman School of Public Health

11:20 – 12:00pm
**PANDEMIC INFLUENZA MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PANEL**

*Moderator: Benjamin Schwartz, M.D.*
Senior Science Advisor, National Vaccine Program Office
Office of Public Health and Science, U.S. Department of Health and Human Services

*Daniel R. Perez, Ph.D.*
Assistant Professor, Virginia – Maryland Regional College of Veterinary Medicine
University of Maryland, College Park

*David Spiro, Ph.D.*
Assistant Investigator, Viral Genomics Group, J. Craig Venter Institute

*Richard J. Whitley, M.D.*
Professor of Pediatric Infectious Diseases, University of Alabama School of Medicine

LUNCH 12:00 – 1:30

1:30 – 1:50pm
**CHEMICAL, BIOLOGICAL, RADIOLICAL, AND NUCLEAR THREAT ASSESSMENTS**

*John Vitko, Ph.D.*
Head, Chem-Bio Division
Science and Technology Directorate, U.S. Department of Homeland Security

1:50 – 2:10pm
**MEDICAL AND PUBLIC HEALTH CONSEQUENCE MODELING: CBRN THREATS AND PANDEMIC INFLUENZA**

*Peter Highnam, Ph.D.*
Lead, BARDA Modeling
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

2:10 – 2:30pm
**USING MODELING FOR MEDICAL COUNTERMEASURE GAP ANALYSIS: THE PANDEMIC INFLUENZA EXAMPLE**

*CAPT Ann Knebel, R.N., D.N.Sc., F.A.A.N.*
Deputy Director for Preparedness Planning, Office of Preparedness and Emergency Operations
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

2:30 – 2:50pm
**SURVEILLANCE AND SITUATIONAL AWARENESS**

*Pamela S. Diaz, M.D.*
Senior Medical Advisor, Division of Bioterrorism Preparedness and Response
Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

2:50 – 3:00pm
**Q AND A**
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| 3:20 – 3:50pm | **Roles in Select Agent Use: U.S. Department of Agriculture and Centers for Disease Control and Prevention** | Lee Ann Thomas, D.V.M., M.S.  
Director, Animals, Organisms, Vectors and Select Agents  
National Center for Import and Export, Plant Protection and Quarantine and Veterinary Services  
Animal and Plant Health Inspection Service, U.S. Department of Agriculture  
Rob Weyant, Ph.D.  
Director of the Division of Select Agents and Toxins  
Coordinating Office for Terrorism, Preparedness and Emergency Response  
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services |
| 3:50 – 4:05pm | **National Institutes of Health - Supporting Investigator Research with Select Agents** | Paula Strickland, Ph.D., M.P.H.  
Director, Office of International Extramural Activities  
Division of Extramural Activities, National Institute of Allergy and Infectious Disease  
National Institutes of Health, U.S. Department of Health and Human Services |
| 4:05 – 4:20pm | **Q & A**                                      |                                                                             |
| 4:20 – 4:40pm | **Food and Drug Administration’s (FDA) Role in Medical Countermeasure Development** | RADM Boris D. Lushniak, M.D., M.P.H.  
Assistant Commissioner, Counterterrorism Policy  
Office of the Commissioner, Office of Counterterrorism and Emerging Threats  
Food and Drug Administration, U.S. Department of Health and Human Services |
| 4:40 – 5:30pm | **Q&A with the FDA**                          | Cynthia L. Kelley, M.S.  
Senior Advisor for Counterterrorism/Medical Countermeasures  
Center for Biologics Evaluation and Research, Food and Drug Administration  
U.S. Department of Health and Human Services  
Rosemary Roberts, M.D.  
Director, Office of Counter-Terrorism and Emergency Coordination  
Center for Drug Evaluation and Research, Food and Drug Administration  
U.S. Department of Health and Human Services  
Alberto Gutierrez, Ph.D.  
Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Patient Safety  
Center for Devices and Radiological Health, Food and Drug Administration  
U.S. Department of Health and Human Services |
PLENARY SESSION IV

8:00 – 8:10am
WELCOME
Carol D. Linden, Ph.D.
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

8:10 – 8:25am
MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PIPELINE – CBRN THREATS
Michael Kurilla, M.D., Ph.D.
Director, Office of BioDefense Research Affairs, Division of Microbiology and Infectious Diseases
Associate Director, BioDefense Product Development, National Institute of Allergy and Infectious Diseases
National Institutes of Health, U.S. Department of Health and Human Services

8:25 – 8:40am
MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PIPELINE – PANDEMIC INFLUENZA
Carole Heilman, Ph.D.
Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases
National Institutes of Health, U.S. Department of Health and Human Services

8:40 – 8:55am
DEPARTMENT OF DEFENSE TRANSFORMATIONAL MEDICAL TECHNOLOGIES INITIATIVE (TMTI)
COL David G. Jarrett, M.D.
Deputy Special Assistant and Medical Director, Office of the Special Assistant for Chemical and Biological Defense
and Chemical Demilitarization Programs, U.S. Department of Defense

8:55 – 9:10am
ANIMAL MODEL DEVELOPMENT
Judith Hewitt, Ph.D.
Chief, Biodefense Research Resources Section
Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases
National Institutes of Health, U.S. Department of Health and Human Services

9:10 – 9:25am
HHS CBRN MEDICAL COUNTERMEASURE ACQUISITIONS – A FORECAST
Monique K. Mansoura, Ph.D.
Acting Deputy Director for Policy, Planning, and Requirements
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

9:25 – 9:40am
PANDEMIC INFLUENZA PHARMACEUTICAL AND NON-PHARMACEUTICAL MEDICAL COUNTERMEASURE ACQUISITIONS – A FORECAST
Robin Robinson, Ph.D.
Director, Pandemic Influenza Program
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

9:40 – 10:00am
Q AND A

BREAK 10:00 - 10:20
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| 10:20 – 10:40 am | Indemnification/Liability Protections under the Public Readiness and Emergency Preparedness (PREP) Act | Dan Barry, J.D. 
Deputy Associate General Counsel, Office of the General Counsel, U.S. Department of Health and Human Services |
| 10:40 – 11:00 am | Intellectual Property Issues in Medical Countermeasure Development            | Julie A. Muroff, J.D. 
Senior Attorney, National Institutes of Health Branch 
Office of the General Counsel, U.S. Department of Health and Human Services |
| 11:00 – 11:20 am | New Provisions under BARDA                                                   | Michael Goulding, J.D. 
Attorney, Procurement, Fiscal and Information Law Branch, General Law Division 
Office of the General Counsel, U.S. Department of Health and Human Services |
| 11:20 – 11:30 am | Q and A                                                                       |                                                                          |
| 1:00 – 1:20 pm | National Response Planning (Emergency Support Function-8)                    | Kevin Yeskey, M.D. 
Deputy Assistant Secretary and Director, Office of Preparedness and Emergency Operations 
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services |
| 1:20 – 1:35 pm | CBRN Medical Countermeasures in Federal Response Planning                     | CAPT Ann Knebel, R.N., D.N.Sc., F.A.A.N. 
Deputy Director for Preparedness Planning, Office of Preparedness and Emergency Operations 
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services |
| 1:35 – 1:50 pm | Pandemic Influenza Medical Countermeasures in Federal Response Planning       | Keith Holtermann, Dr.P.H., M.B.A., M.P.H., R.N. 
Special Assistant, Office of Preparedness and Emergency Operations 
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services |
| 1:50 – 2:05 pm | Strategic National Stockpile Utilization and Deployment                       | Greg Burel 
Acting Director, Division of Strategic National Stockpile 
Coordinating Office for Terrorism Preparedness and Emergency Response 
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services |
| 2:05 – 2:20 pm | Federal Cooperation with State, Local, and Tribal Response                   | Christa-Marie Singleton, M.D., M.P.H. 
Associate Director for Science, Division of State and Local Readiness 
Coordinating Office for Terrorism Preparedness and Emergency Response 
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services |
| 2:20 – 2:30 pm | Q and A                                                                       |                                                                          |
2:45 – 3:05 pm  **MEDICAL COUNTERMEASURE DEVELOPMENT AND ACQUISITION: THE PATH FORWARD UNDER THE HHS PANDEMIC INFLUENZA PLAN**

*Benjamin Schwartz, M.D.*
Senior Science Advisor, National Vaccine Program Office
Office of Public Health and Science, U.S. Department of Health and Human Services

3:05 – 3:30 pm  **MEDICAL COUNTERMEASURE DEVELOPMENT AND ACQUISITION: THE PATH FORWARD UNDER THE HHS PHEMCE IMPLEMENTATION PLAN FOR CBRN THREATS**

*Carol D. Linden, Ph.D.*
Principal Deputy Director and Acting Director, Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services