



**HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop**

The Fairmont Hotel Washington  
Washington, DC  
July 31–August 2, 2007



**Registration Desk Open 7:00am – 7:00pm Ballroom Foyer**

**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, Department of Health and Human Services
- RADM W. Craig Vanderwagen, M.D.*  
Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- Secretary Michael O. Leavitt*  
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, 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, Department of Health and Human Services

**PLENARY SESSION I**

Chemical, Biological, Radiological, and Nuclear (CBRN) Medical Countermeasure Preparedness

- 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, 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, Department of Health and Human Services
- 9:45 – 10:00am **FOOD AND DRUG ADMINISTRATION'S CBRN MEDICAL COUNTERMEASURE ACTIVITIES**  
*Janet Woodcock, M.D.*  
Deputy Commissioner and Chief Medical Officer, Office of the Commissioner  
Food and Drug Administration, Department of Health and Human Services
- 10:00 – 10:15am **DEPARTMENT OF HOMELAND SECURITY ADDRESS**  
*Jeff Runge, M.D.*  
Assistant Secretary for Health Affairs and Chief Medical Officer, 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, Department of Defense

**B R E A K 10:30 - 10:50 Ballroom Foyer**

**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, 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, 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

*Debra 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  
Chairman, Department of Radiation Oncology, University of Rochester Cancer Center

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, Department of Health and Human Services

*James J. James, M.D., Dr.P.H., M.H.A.*

Director, Center for Disaster Preparedness and Emergency Response, American Medical Association

*Kristen Welker-Hood, D.Sc., M.S.N., R.N.*

Senior Policy Fellow, 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, Department of Health and Human Services

*Paul E. Jarris, M.D.*

Executive Director, Association of State and Territorial Health Officials

*Jack Hermann*

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

*Jacqueline L. Johnson*

Executive Director, National Congress of American Indians

**LUNCH ON YOUR OWN 12:30 - 2:00**

**SIMULTANEOUS WORK SESSIONS**

Medical Countermeasure  
Planning and Implementation

2:00 – 3:30pm

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

*Group A1*                      *Location: Ballroom I*  
*Group A2*                      *Location: Ballroom II*  
*Group A3*                      *Location: Lord Culpeper Room*

**FEDERAL PARTNERSHIP WITH STATE, LOCAL, AND TRIBAL AUTHORITIES IN PREPAREDNESS AND RESPONSE**

*Group B1*                      *Location: Alice Longworth Room*  
*Group B2*                      *Location: Benjamin Latrobe Room*

**INCENTIVIZING PRIVATE INDUSTRY TO SUPPORT CBRN MEDICAL COUNTERMEASURE PREPAREDNESS**

*Group C1*                      *Location: Decatur Room*  
*Group C2*                      *Location: Lindens Suite, Third Floor*

**MEDICAL COUNTERMEASURE CONCEPT OF OPERATIONS: MAKING THE CONNECTION BETWEEN DEVELOPMENT AND END USER UTILITY**

*Group D1*                      *Location: Potomac Suite, Third Floor*

**TECHNOLOGICAL INNOVATIONS TO IMPROVE MEDICAL COUNTERMEASURE RESPONSE AND TO MEET THE CHALLENGE OF NOVEL AND EMERGING THREATS**

*Group E1*                      *Location: Dumbarton Suite, Third Floor*

**B R E A K   3:30 - 3:50   Ballroom Foyer**

**SEMINAR SESSION I**

Contracting with HHS  
for Medical Countermeasure Development and Acquisition

3:50 – 3:55pm

**OPENING**

*RoseMary Mann*  
Contracting Officer, Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response, 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, 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, Department of Health and Human Services

4:40 – 4:55pm

**CENTERS 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  
Centers for Disease Control and Prevention, 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, Department of Health and Human Services

5:10 – 5:30pm

**Q AND A**

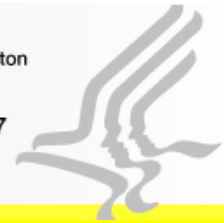
**NETWORKING SOCIAL   5:30 - 7:00   Ballroom Foyer**



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**PLENARY SESSION II**  
Pandemic Influenza Medical Countermeasure Preparedness

- 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, Department of Health and Human Services
- 8:10 – 8:30am **NATIONAL PANDEMIC INFLUENZA PLAN**  
*Rajeev Venkayya, M.D.*  
Special Assistant to the President for Biodefense, Homeland Security Council, Executive Office of the President
- 8:30 – 8:45am **HHS PANDEMIC INFLUENZA IMPLEMENTATION PLAN – PROGRESS TO DATE**  
*ADM John O. Agwunobi, M.D., M.B.A., M.P.H.*  
Assistant Secretary for Health  
Department of Health and Human Services
- 8:45 – 9:00am **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE IMPLEMENTATION ACTIVITIES**  
*Gerald W. Parker, D.V.M., Ph.D., M.S.*  
Principal Deputy Assistant Secretary  
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- 9:00 – 9:15am **NATIONAL VACCINE PROGRAM OFFICE’S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**  
*Bruce Gellin, M.D., M.P.H.*  
Director, National Vaccine Program Office, Department of Health and Human Services
- 9:15 – 9:30am **NATIONAL INSTITUTES OF HEALTH’S PANDEMIC INFLUENZA IMPLEMENTATION ACTIVITIES**  
*Roland A. Levandowski, M.D.*  
Chief, Influenza, SARS and Other Viral Respiratory Diseases Section, Respiratory Diseases Branch  
Division of Microbiology and Infectious Diseases, National Institutes of Health, Department of Health and Human Services
- 9:30 – 9:45am **CENTERS FOR DISEASE CONTROL AND PREVENTION’S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**  
*CAPT Stephen Redd, M.D.*  
Influenza Team Lead, Coordinating Center for Infectious Diseases  
Centers for Disease Control and Prevention, Department of Health and Human Services
- 9:45 – 10:00am **FOOD AND DRUG ADMINISTRATION’S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**  
*Mark Goldberger, M.D., M.P.H.*  
Medical Director for Emerging and Pandemic Threat Preparedness, Center for Biologics Evaluation and Research  
Food and Drug Administration, Department of Health and Human Services
- 10:00 – 10:15am **DEPARTMENT OF DEFENSE PANDEMIC INFLUENZA ACTIVITIES**  
*LTC Wayne E. Hachey, D.O., M.P.H.*  
Director Preventive Medicine, Office of the Assistant Secretary of Defense (Health Affairs)  
Force Health Protection and Readiness, Department of Defense

**B R E A K 10:15 - 10:35 Ballroom Foyer**

**PANEL SESSION II**

Stakeholder Pandemic Influenza  
Medical Countermeasure Preparedness Efforts

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, 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, 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, J. Craig Venter Institute

*Richard J. Whitley, M.D.*

Professor of Pediatric Infectious Diseases, University of Alabama School of Medicine

**LUNCH ON YOUR OWN 12:00 - 1:30**

**PLENARY SESSION III**

CBRN and Pandemic Influenza  
Threats and Medical/Public Health Consequences

1:30 – 1:50pm

**CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR THREAT ASSESSMENTS**

*John Vitko, Ph.D.*

Director of Biological and Chemical Countermeasures, Science and Technology Directorate  
Department of Homeland Security

1:50 – 2:10pm

**MEDICAL AND PUBLIC HEALTH CONSEQUENCE MODELING: CBRN THREATS AND PANDEMIC INFLUENZA**

*Peter Highnam, Ph.D.*

Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response, 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, 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  
Department of Health and Human Services

2:50 – 3:00pm

**Q AND A**

**B R E A K 3:00 - 3:20 Ballroom Foyer**

**SEMINAR SESSION II**  
Select Agent Regulations

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, 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, Department of Health and Human Services

3:50 – 4:05pm

**NATIONAL INSTITUTES OF HEALTH - SUPPORTING INVESTIGATOR RESEARCH WITH SELECT AGENTS**

*Paula Strickland, Ph.D.*

Director, Office of International Extramural Activities, National Institute of Allergy and Infectious Disease  
National Institutes of Health, Department of Health and Human Services

4:05 – 4:20pm

**Q AND A**

**SEMINAR SESSION III**  
FDA Regulations, Roles, and Responsibilities  
in Medical Countermeasure Development

4:20 – 4:40pm

**FOOD AND DRUG ADMINISTRATION'S (FDA) ROLE IN MEDICAL COUNTERMEASURE DEVELOPMENT**

*RADM Boris Lushniak, M.D., M.P.H.*

Assistant Commissioner, Office of Counterterrorism Policy and Planning  
Food and Drug Administration, 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  
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  
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  
Department of Health and Human Services



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**PLENARY SESSION IV**  
Medical Countermeasure Research, Development, and Acquisition

- 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, 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 Activities, Division of Microbiology and Infectious Diseases  
Associate Director for Biodefense Product Development, National Institute of Allergy and Infectious Diseases  
National Institutes of Health, 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, Department of Health and Human Services
- 8:40 – 8:55am **DEPARTMENT OF DEFENSE TRANSFORMATIONAL MEDICAL TECHNOLOGIES INITIATIVE (TMTI)**  
*COL David G. Jarrett, MC, USA*  
Deputy Special Assistant and Medical Director, Chemical Biological Defense Programs  
Department of Defense
- 8:55 – 9:10am **ANIMAL MODEL DEVELOPMENT**  
*Judith Hewitt, Ph.D.*  
Research Resources Program Officer, National Institute of Allergy and Infectious Diseases  
National Institutes of Health, 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, 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.*  
Acting Associate Director, Office of Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- 9:40 – 10:00am **Q AND A**

**B R E A K 10:00 - 10:20 Ballroom Foyer**

**SEMINAR SESSION IV**

Liability Immunity Protections, Intellectual Property Issues, and Biomedical Advanced Research and Development Authority Provisions

- 10:20 – 10:40am **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, Department of Health and Human Services
- 10:40 – 11:00am **Intellectual Property Issues in Medical Countermeasure Development**  
*Julie A. Muroff, J.D.*  
 Senior Attorney, Office of the General Counsel, Public Health Division  
 National Institutes of Health Branch, Department of Health and Human Services
- 11:00 – 11:20am **New Provisions under BARDA**  
*Michael Goulding, J.D.*  
 Attorney, Office of the General Counsel, Department of Health and Human Services
- 11:20 – 11:30am **Q and A**

**LUNCH ON YOUR OWN 11:30 - 1:00**

**PLENARY SESSION V**

Medical Countermeasures and Federal Response Planning

- 1:00 – 1:20pm **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, Department of Health and Human Services
- 1:20 – 1:35pm **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, Department of Health and Human Services
- 1:35 – 1:50pm **PANDEMIC INFLUENZA MEDICAL COUNTERMEASURES IN FEDERAL RESPONSE PLANNING**  
*Keith Holtermann, Dr.P.H., M.B.A., M.P.H., R.N.*  
 Office of Preparedness and Emergency Operations  
 Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- 1:50 – 2:05pm **STRATEGIC NATIONAL STOCKPILE UTILIZATION AND DEPLOYMENT**  
*Greg Burel*  
 Acting Director, Division of Strategic National Stockpile  
 Centers for Disease Control and Prevention, Department of Health and Human Services
- 2:05 – 2:20pm **FEDERAL COOPERATION WITH STATE, LOCAL, AND TRIBAL RESPONSE**  
*Christa Singleton, M.D., M.P.H.*  
 Associate Director for Science, Division of State and Local Readiness  
 Centers for Disease Control and Prevention, Department of Health and Human Services
- 2:20 – 2:30pm **Q AND A**

**BREAK 2:30 - 2:45 Ballroom Foyer**

**CLOSING SESSION**

2:45 – 3:05 pm

**MEDICAL COUNTERMEASURE DEVELOPMENT AND ACQUISITION: THE PATH FORWARD UNDER THE HHS PANDEMIC INFLUENZA PLAN**

*Bruce Gellin, M.D., M.P.H.*

Director, National Vaccine Program Office, 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, Department of Health and Human Services