



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

The Fairmont Hotel Washington
Washington, DC

July 31–August 2, 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

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, 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

B R E A K 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

SIMULTANEOUS WORK SESSIONS

Medical Countermeasure
Planning and Implementation

2:00 – 3:30pm

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) 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

B R E A K 3:30 - 3:50

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, 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

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
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

5:10 – 5:30pm

Q AND A

NETWORKING SOCIAL 5:30 - 7:00



- 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 – 8:30am **NATIONAL PANDEMIC INFLUENZA PLAN**
Kenneth Staley, M.D., M.P.A.
Director for Biodefense Policy, 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, U.S. Department of Health and Human Services
- 8:45 – 9:00am **NATIONAL VACCINE PROGRAM OFFICE’S PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**
Bruce Gellin, M.D., M.P.H.
Director, National Vaccine Program Office
Office of Public Health and Science, U.S. Department of Health and Human Services
- 9:00 – 9:15am **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, U.S. 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 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 PANDEMIC INFLUENZA PLAN IMPLEMENTATION ACTIVITIES**
CAPT Stephen C. Redd, M.D.
Director, Influenza Coordination Unit
Centers for Disease Control and Prevention, U.S. 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, U.S. 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, U.S. Department of Defense

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, 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

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.

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

B R E A K 3:00 - 3:20

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, 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 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 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



- 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**

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, U.S. Department of Health and Human Services
- 10:40 – 11:00am **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 – 11:20am **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 – 11:30am **Q and A**

LUNCH 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, U.S. 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, U.S. 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.
 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 – 2:05pm **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 – 2:20pm **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 – 2:30pm **Q AND A**

BREAK 2:30 - 2:45

CLOSING SESSION

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