

HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop The Fairmont Hotel Washington Washington, DC

July 31-August 2, 2007

		8:00 – 8:25am	WELCOME AND OPENING SESSION
			<i>Carol D. Linden, Ph.D.</i> 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
	ion		RADM W. Craig Vanderwagen, M.D. Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services
	šessi		Secretary Michael O. Leavitt U.S. Department of Health and Human Services
	ğ	8:25 – 8:45am	PANDEMIC AND ALL-HAZARDS PREPAREDNESS
	Opening Session		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
			<i>Carol D. Linden, Ph.D.</i> 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
	SRN)		Rajeev Venkayya, M.D. Special Assistant to the President for Biodefense, Homeland Security Council, Executive Office of the President
	Radiological, and Nuclear (CBRN) termeasure Preparedness	9:15 – 9:30am	NATIONAL INSTITUTES OF HEALTH'S CBRN MEDICAL COUNTERMEASURE ACTIVITIES
ARY SESSION I			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
	and N Prepar	9:30 – 9:45am	CENTERS FOR DISEASE CONTROL AND PREVENTION'S CBRN MEDICAL COUNTERMEASURE ACTIVITIES
	Radiological, ermeasure P		Greg Burel Acting Director, Division of Strategic National Stockpile Centers for Disease Control and Prevention, U.S. Department of Health and Human Services
RV	adic :rme	9:45 – 10:00am	FOOD AND DRUG ADMINISTRATION'S CBRN MEDICAL COUNTERMEASURE ACTIVITIES
LENA	cal, R counte		Andrew C. von Eschenbach, M.D. Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services
_	logi al C	10:00 – 10:15am	DEPARTMENT OF HOMELAND SECURITY ADDRESS
	Chemical, Biological, R Medical Count		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
G	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
akeholder Respon	11:15 – 11:35am	Senior Vice President and Chief Financial Officer, Pharmaceutical Research and Manufacturers of America ACADEMIA/ SCIENCE PANEL <i>Moderator: Carol D. Linden, Ph.D.</i> 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 <i>Tara O'Toole, M.D., M.P.H.</i>
:SSION I aredness Efforts – St		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
PANEL SESSION I HHS CBRN Medical Countermeasure Preparedness Efforts – Stakeholder Response	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
HHS CBRN Medic	12:05 – 12:25pm	 Georges C. Benjamin, M.D. Executive Director, American Public Health Association 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

2:00 - 3:30pm **BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA) IMPLEMENTATION** SIMULTANEOUS WORK SESSIONS Groups A1, A2, and A3 Implementation FEDERAL PARTNERSHIP WITH STATE, LOCAL, AND TRIBAL AUTHORITIES IN PREPAREDNESS Medical Countermeasure AND RESPONSE Groups B1 and B2 INCENTIVIZING PRIVATE INDUSTRY TO SUPPORT CBRN MEDICAL COUNTERMEASURE **PREPAREDNESS** ig and Groups C1 and C2 MEDICAL COUNTERMEASURE CONCEPT OF OPERATIONS: MAKING THE CONNECTION BETWEEN DEVELOPMENT AND END USER UTILITY Planni Group D1 TECHNOLOGICAL INNOVATIONS TO IMPROVE MEDICAL COUNTERMEASURE RESPONSE AND TO MEET THE CHALLENGE OF NOVEL AND EMERGING THREATS Group E1 BREAK 3:30 - 3:50 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 FEDERAL ACQUISITION REQUIREMENTS (FAR) 101 AND BARDA CONTRACTING 3:55 - 4:25pm 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 Development 4:25 - 4:40pm **NATIONAL INSTITUTES OF HEALTH RESEARCH AND DEVELOPMENT ACQUISITION** Contracting with HHS **SEMINAR SESSION 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 ountermeasure CENTERS FOR DISEASE CONTROL AND PREVENTION. DIVISION OF THE STRATEGIC 4:40 - 4:55pm **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 MEDICALCOUNTERMEASURES.GOV (A STAKEHOLDER PORTAL) 4:55 - 5:10pm 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



PLENARY SESSION II

HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop The Fairmont Hotel Washington Washington, DC

July 31-August 2, 2007

	8:00 – 8:10am	WELCOME	
		<i>Carol D. Linden, Ph.D.</i> 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	
Iness		ADM John O. Agwunobi, M.D., M.B.A., M.P.H. Assistant Secretary for Health, U.S. Department of Health and Human Services	
Pandemic Influenza Medical Countermeasure Preparedness	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	
		<i>Mark Goldberger, M.D., M.P.H.</i> 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	
		<i>LTC Wayne E. Hachey, D.O., M.P.H.</i> Director Preventive Medicine, Office of the Assistant Secretary of Defense (Health Affairs) Force Health Protection and Readiness, U.S. Department of Defense	
	B R E A K 10:15 - 10:35		

	10:35 – 11:15am	PANDEMIC INFLUENZA ANTIVIRAL DRUG STOCKPILE PARTNERING PANEL
		<i>Moderator: Arthur Y. Elliot, M.D., Ph.D.</i> 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
Efforts		<i>Dominick Iacuzio, Ph.D.</i> Medical Director, Hoffman-La Roche, Inc.
		Adam Kesselman Relenza Global Product Director, GlaxoSmithKline
ON II iic Influ epared		Susan C. Penfield, M.D. Manager, Infectious Disease Control Unit, Texas State Department of Health
PANEL SESSION II Stakeholder Pandemic Influenza Medical Countermeasure Preparedness		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
NE der me	11:20 – 12:00pm	PANDEMIC INFLUENZA MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PANEL
PA takeholi Counter		<i>Moderator: Benjamin Schwartz, M.D.</i> Senior Science Advisor, National Vaccine Program Office Office of Public Health and Science, U.S. Department of Health and Human Services
S Medical (Daniel R. Perez, Ph.D. Assistant Professor, Virginia – Maryland Regional College of Veterinary Medicine University of Maryland, College Park
		<i>David Spiro, Ph.D.</i> 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, RADIOLOGICAL, AND NUCLEAR THREAT ASSESSMENTS
lences		John Vitko, Ph.D. Head, Chem-Bio Division Science and Technology Directorate, U.S. Department of Homeland Security
III uenza Consedu	1:50 – 2:10pm	MEDICAL AND PUBLIC HEALTH CONSEQUENCE MODELING: CBRN THREATS AND PANDEMIC INFLUENZA
N III nfluer th Cc		Peter Highnam, Ph.D. Lead, BARDA Modeling
SSION emic Infl Health		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
XY SES Panden /Public I	2:10 – 2:30pm	Using Modeling for Medical Countermeasure Gap Analysis: The Pandemic Influenza Example
PLENARY SESSION III CBRN and Pandemic Influenza Chreats and Medical/Public Health Consi		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
P BR	2:30 – 2:50pm	SURVEILLANCE AND SITUATIONAL AWARENESS
) Cats an		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

B R E A K 3:00 - 3:20			
ION II Jations	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.	
SEMINAR SESSION II Select Agent Regulations	3:50 – 4:05pm	Not 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 NATIONAL INSTITUTES OF HEALTH - SUPPORTING INVESTIGATOR RESEARCH WITH SELECT	
		Agents	
SEN Sele		<i>Paula Strickland, Ph.D., M.P.H.</i> 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	
ties nt	4:20 – 4:40pm	FOOD AND DRUG ADMINISTRATION'S (FDA) ROLE IN MEDICAL COUNTERMEASURE DEVELOPMENT	
III sponsibili velopmer		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	
De Re	4:40 – 5:30pm	Q&A WITH THE FDA	
MINAR SESSION III ions, Roles, and Responsibiliti Countermeasure Development		<i>Cynthia L. Kelley, M.S.</i> Senior Advisor for Counterterrorism/Medical Countermeasures Center for Biologics Evaluation and Research, Food and Drug Administration U.S. Department of Health and Human Services	
SEMINAR SESSION III FDA Regulations, Roles, and Responsibilities in Medical Countermeasure Development		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	
SE FDA Regulat in Medical		Alberto Gutierrez, Ph.D. Deputy Director, Office of <i>In Vitro</i> 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

HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop The Fairmont Hotel Washington Washington, DC

July 31-August 2, 2007

	8:00 – 8:10am	WELCOME	
		<i>Carol D. Linden, Ph.D.</i> 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	
nd Acquisition	8:10 – 8:25am	MEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT PIPELINE - CBRN THREATS	
		<i>Michael Kurilla, M.D., Ph.D.</i> 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	
ment, a		<i>Carole Heilman, Ph.D.</i> 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	
evelop	8:40 – 8:55am	DEPARTMENT OF DEFENSE TRANSFORMATIONAL MEDICAL TECHNOLOGIES INITIATIVE (TMTI)	
arch, De		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	
Medical Countermeasure Research, Development, and Acquisition	8:55 – 9:10am	ANIMAL MODEL DEVELOPMENT	
		<i>Judith Hewitt, Ph.D.</i> 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	
	B R E A K 10:00 - 10:20		

SEMINAR SESSION IV	Liability Immunity Protections, Intellectual Property Issues, and	siomedical Advanced Research and Development Authority Provisio
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PLENARY SESSION V Medical Countermeasures and Federal Response Planning

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			
1:00 – 1:20pm	NATIONAL RESPONSE PLANNING (EMERGENCY SUPPORT FUNCTION-8)			
	<i>Kevin Yeskey, M.D.</i> 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			
	<i>Keith Holtermann, Dr.P.H., M.B.A., M.P.H., R.N.</i> 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
		<i>Carol D. Linden, Ph.D.</i> 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