



Medical Countermeasures Dispensing: Emergency Use Authorization

November 18, 2009
Keck Center, Room 100
500 5th St, NW
Washington, DC 20001

Workshop Objectives:

Building upon the recent progress in countermeasure delivery and dispensing strategies, the objectives of this workshop are to:

- Provide an overview of the current threats, progress made, and remaining vulnerabilities in the public health system as it pertains to the dispensing of medical countermeasures.
- Discuss policy implications of emergency use authorization (EUA) and strategies to limit potential logistical challenges that could delay the delivery and dispensing of medical countermeasures.
- Discuss outstanding issues related to emergency use authorizations and how these issues are impacting the nation's preparedness and response capabilities.

8:30 a.m. Welcome and Introductions

LEWIS GOLDFRANK, *Forum Chair*
Professor and Chair
Department of Emergency Medicine
New York University School of Medicine

8:40 a.m. Charge to Workshop Speakers and Participants

GREGORY BUREL, *Workshop Co-Chair*
Director
Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

SCOTT MUGNO, *Workshop Co-Chair*
Managing Director
Corporate Safety Health and Fire Protection
FedEx

**SESSION I: OVERVIEW AND NEW POLICIES TO IMPROVE MEDICAL
COUNTERMEASURE DISPENSING**

Session Objective: Provide an overview of the current threats, progress made, and remaining vulnerabilities in the public health system as it pertains to the dispensing of medical countermeasures, including both antibiotics and antivirals.

GREGORY BUREL, *Session Chair and Workshop Co-Chair*
Director
Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

9:00 a.m. Federal Policy Developments Related to Countermeasure Dispensing

MATTHEW MINSON
Senior Medical Officer for Strategic Initiatives
Office of the Assistant Secretary for Preparedness and Response, HHS

9:15 a.m. State and Local Opportunities and Challenges

JAMES BLUMENSTOCK
Senior Director, Public Health Preparedness
Association of State and Territorial Health Officials

JACK HERRMANN
Senior Advisor
Public Health Preparedness
National Association of County and City Health Officials

9:30 a.m. Dispensing Antibiotic Countermeasures: Progress, Opportunities, and Challenges:
Moving Forward from the Prep Act

BROOKE COURTNEY
Associate
Center for Biosecurity of UPMC

9:45 a.m. Dispensing Antiviral Countermeasures: Progress, Opportunities, and Challenges
from the Local Response to H1N1

GREGORY BUREL
Director
Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

10.00 a.m. A Systems View of POD Operations: Integrating all the Elements

EVA LEE

Director, Center for Operations Research in Medicine and HealthCare
Associate Professor, School of Industrial and Systems Engineering
Georgia Institute of Technology

10:15 a.m. Discussion with attendees

- How have previous policy decisions prepared the nation for the H1N1 response?
- What are the lessons learned from the H1N1 response to-date?
- Are there specific areas that require additional attention as we move forward in responding to the next influenza wave or preparing for other biological threats?
 - What were some of the differences between state and local MCM allocation plans, and how did these impact the overall effectiveness of their plans?
- What are some the key difference differences between antibiotic and antiviral dispensing plans, and how should these impact future policy discussions?

GREGORY BUREL, *Session Chair and Workshop Co-Chair*
Director

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10:35 a.m. Break

SESSION II: EMERGENCY USE AUTHORIZATION: STRATEGIES TO LIMIT POTENTIAL LOGISTICAL CHALLENGES

Session Objective: Explore the impact of emergency use authorization (EUA) and strategies to limit potential logistical challenges that could delay the delivery and dispensing of medical countermeasures.

10:45 a.m. Understanding the EUA Process: Authorization for Medical Products for a Catastrophic Health Event

CDR CARMEN MAHER

Policy Analyst/Senior Nurse Officer

Office of Counterterrorism and Emerging Threats

Food and Drug Administration

11:00 a.m. Panel Discussion: Lessons Learned from Recent EUA Signings: H1N1 and the Minneapolis Postal Plan

SUSAN GORMAN, *Panel Chair*
Associate Director for Science
Division of Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency
Response
Centers for Disease Control and Prevention

SUSAN SHERMAN
Senior Attorney
Office of the General Counsel, HHS

KEVIN SELL
Pharmacist Consultant
Office of Emergency Preparedness
Minnesota Department of Health and
Minnesota Poison Control System

JUDE PLESSAS
Operations Specialist
United States Postal Service

BRAD LEISSA
Deputy Director & CDER Emergency Coordinator
Office of Counter-Terrorism and Emergency Coordination
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration

- 11:30 a.m. Discussion with panelists and attendees
- What is the “update from the field”?
 - Have any previously identified impediments been successfully addressed during the recent activity around H1N1?
 - Have any new glaring problems emerged?
 - What remaining impediments related to EUA continue to delay the dispensing of medical countermeasures?
 - What strategies or mechanisms can be used to address these impediments, and how can they be implemented?
 - What potential solutions should be highlighted?

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Associate Director for Science
Division of Strategic National Stockpile
Coordinating Office for Terrorism Preparedness and Emergency
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12:15 p.m. Lunch (Continued discussion: EUA Continued Challenges)

1:00 p.m. Panel Discussion: Pre-EUA Issues related to Communication Strategies

AGGIE LEITHEISER, *Panel Chair*
Director of Emergency Preparedness
Minnesota Department of Health

GRETCHEN MICHAEL
Communications Director
HHS, ASPR

LAURA ROSS
Health Communication Specialist
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

PAMELA BLACKWELL
Director
Center for Emergency Preparedness and Response
Cobb & Douglas Public Health

1:30 p.m. Discussion with panelists and attendees

- What can be done during the pre-EUA's process to account for the logistical challenges associated with printing and disseminating information to the public in a timely manner?
- How can EUA's be modified during an event to facilitate timely communication during an incident?
- How can Web 2.0 technologies be leveraged to alleviate challenges related to disseminating information to the public in a timely manner?
- How do we prepare for issues such as producing materials in multiple languages or for people with low literacy?
- How do we deal with guidance that may change every day, as was the case with H1N1?

AGGIE LEITHEISER, *Panel Chair*
Director of Emergency Preparedness
Minnesota Department of Health

2:15 p.m. Panel Discussion: Workforce Protection

KATHRYN BRINSFIELD, *Panel Chair*
Associate Chief Medical Officer
Office of Component Services
Office of Health Affairs, DHS

TIM STEPHENS
Public Health Advisor
National Sheriff's Association

LAURA EIKLENBORG
Director, Solutions Development
OptumHealth Public Sector

TIMOTHY CONLEY
Village of Western Springs Emergency Preparedness Planning Director
Western Springs Fire Department and Emergency Medical Services

- 2:45 p.m. Discussion with panelists and attendees
- How should priorities be set and what are the best mechanisms to ensure that workers get the protection they need?
 - How can we effectively communicate with workers prior to an emergency?
 - What operational issues need to be considered to ensure that the workforce is protected?
 - What are the respective responsibilities of the public and private stakeholders, and how should they function together?

KATHRYN BRINSFIELD, *Panel Chair*
Associate Chief Medical Officer
Office of Component Services
Office of Health Affairs, DHS

<p>SESSION III: GENERAL DISCUSSION WITH WORKSHOP PARTICIPANTS AND ATTENDEES</p>
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Session Objective: Discuss opportunities and constraints identified during the workshop. What new ideas have surfaced in this meeting today that should be explored further? What issues remain related to emergency use authorizations and their impact on the nation's preparedness and response, and how should these issues be addressed?

- 3:30 p.m. Panel Discussion: Remaining Areas that Require Attention: e.g. workforce, liability, security, logistics, communications

SCOTT MUGNO, *Session Chair and Workshop Co-Chair*
Managing Director
Corporate Safety Health and Fire Protection
FedEx

GLORIA ADDO-AYENSU
Health Director
Fairfax County Health Department, Virginia

ATKINSON (JACK) LONGMIRE
Medical Officer
OSHA Office of Occupational Medicine

MITCHEL ROTHHOLZ
Chief of Staff
American Pharmacists Association

DARRELL KLEIN
Assistant Agency Counsel
Nebraska Health and Human Services

- 4:00 p.m. Moderated Discussion with Attendees
- What other issues related to EUA have not yet been discussed during the workshop, for example, issues regarding liability, security, and logistics?
 - What strategies, mechanisms, or solutions can be used to address these issues, and how can they be implemented?

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- 4:45 p.m. Closing Remarks

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