Medical Product Shortages during Disasters: Opportunities to Predict, Prevent, and Respond
A Workshop

Final Agenda
Wednesday, September 5, 2018 – Thursday, September 6, 2018
National Academy of Sciences Building – Fred Kavli Auditorium
2101 Constitution Avenue, N.W., Washington, D.C., 20418

Workshop Objectives

- Explore the current evidence base on the causes and effects of medical product shortages that result from disasters or other public-health emergencies on patient care, patient outcomes, and provider resource allocation and availability.
- Discuss current efforts and innovative approaches to better predict, prevent, and respond to medical product shortages that result from disasters or other public-health emergencies.
- Examine strategies to ensure public health and health care providers can provide high-quality patient care during shortages of medical product shortages.
- Identify research needs and opportunities to provide public-health officials and the general public with accurate information to support policy-making and decision-making to improve patient care.

Day 1 - September 5, 2018

Session I  Welcome and Overview of the Workshop

8:30 a.m.  Chair Welcome

W. Craig Vanderwagen, Workshop Chair
Co-Founder and Director
East West Protection, LLC

8:45 a.m.  Opening Keynote

Kevin Yeskey
Principal Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
Objectives

- Overview the supply chain and production of medical products, focusing on common disruptions that contribute to medical product shortages and their causes.
- Consider how public health emergencies exacerbate existing disruptions in the supply chain.
- Discuss the economic drivers contributing to medical product shortages.
- Examine the current state of medical product shortages in the U.S. and how these shortages impact various stakeholder groups, including patients, caregivers, providers, and other vulnerable populations.
- Explore how medical product shortages during a public health emergency may contribute to medical errors, health care quality, patient and provider safety, provider resource allocation, and cost.

9:15 a.m. Panel Discussion I: Establishing a Shared Understanding of Medical Product Shortages – A Complex Challenge

Moderator: W. Craig Vanderwagen, Workshop Chair
Co-Founder and Director
East West Protection, LLC

Speakers:

Douglas Throckmorton
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services

Ernst R. Berndt
Professor, Applied Economics
Massachusetts Institute of Technology

Scott Knoer
Chief Pharmacy Officer
Cleveland Clinic

James Callahan
Senior Director, Global Business Resilience
Enterprise Risk Management
AmerisourceBergen

10:15 a.m. Audience Q&A

10:45 a.m. BREAK

11:00 a.m. Panel Discussion II: Effects of Medical Product Shortages on Patients, Providers, and Systems
**Moderator:** Linda Rouse O’Neill  
Vice President, Government Affairs  
Healthcare Industry Distributors Association

**Speakers:**

**Mike Bowen**  
Spokesperson, Secure Mask Supply Association  
Executive Vice President  
Prestige Ameritech

**Steve Krug**  
Head, Pediatric Emergency Medicine  
Professor of Pediatrics, Northwestern University Feinberg School of Medicine  
American Academy of Pediatrics

**Allen J. Vaida**  
Executive Vice President  
Institute for Safe Medication Practices

**Bonnie Levin**  
Corporate Assistant Vice President, Pharmacy Services  
MedStar Health

**James Robinson**  
Assistant Chief, Paramedic Division  
Denver Health Emergency Medical Services

**Audience Q&A**

**12:30 p.m.**  
**LUNCH**

**Session III**  
**Predicting, Preventing, and Responding to Medical Product Shortages: Current Efforts and Challenges**

**Objectives**

- Overview the strengths and limits of current efforts used to monitor, prevent, and control medical product shortages  
- Discuss the advantages and disadvantages of the complex and multisector nature of medical product development  
- Examine different stakeholder roles and evidence needs to support decision making and identify shared goals to prevent, predict, and respond to shortages  
- Identify the challenges and gaps to predicting, preventing, and responding to shortages

**1:30 p.m.**  
**Panel Discussion III: Current Efforts to Predict, Prevent, and Respond**

**Moderator:** Sara Roszak  
Senior Director, Research Programs
National Association of Chain Drug Stores

 Speakers:

 Keagan Lenihan
 Associate Commissioner, Strategic Initiatives
 Food and Drug Administration
 Department of Health and Human Services

 Mary Kosinski
 Chief of Staff and Deputy Vice President
 Science & Regulatory Advocacy
 Pharmaceutical Research and Manufacturers of America

 Karla Miller
 Vice President, Pharmacy Services and Clinical Therapeutics
 Clinical Services Group
 Hospital Corporation of America

 Patrick Byrne
 Logistics Management Specialist
 Biomedical Advanced Research and Development Authority
 Office of the Assistant Secretary for Preparedness and Response
 Department of Health and Human Services

 François Sallans
 Chairman of the International Society for Pharmaceutical Engineering Drug
 Shortages Committee
 Chief Quality Officer of Johnson & Johnson

 2:30 p.m.  Audience Q&A

 3:00 p.m.  BREAK

 3:15 p.m.  Panel Discussion IV: Gaps and Challenges

 Moderator: Nicolette Louissaint
 Executive Director
 Healthcare Ready

 Speakers:

 Brad Noe
 Global Manager, Technical Resources Hypodermic Business
 Becton Dickinson

 Michael Ganio
 Director, Pharmacy Practice and Quality
 American Society of Health-System Pharmacists
**Session IV**  
**Scenario-based Facilitated Discussion**

**Description**  
- A fictional medical product shortage scenario will be introduced and panelists and workshop participants will be asked to answer questions about how they would adapt to this situation.
- Four different situations will be considered:
  - Disruption of known duration vs. unknown duration
  - Shortage of known duration vs. unknown duration
  - Shortage due to high demand vs. shortage due to low supply
  - Shortage of response specific needs vs. routine care needs

**4:15 p.m.**  
**Medical Product Shortage Scenario**

*Moderator: Matthew Wynia*  
Director, Center for Bioethics and Humanities  
Professor of Medicine  
University of Colorado

*Speakers:*

**James Hodge**  
Professor, Public Health Law and Ethics  
Director, Center for Public Health Law and Policy  
Sandra Day O’Connor College of Law

**Lewis Rubinson**  
Professor of Medicine  
University of Maryland  
Vice President, Deputy Chief Clinical Officer  
University of Maryland Medical Center

**Monique K. Mansoura**  
Executive Director, Global Health Security and Biotechnology  
The MITRE Corporation
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<td>5:15 p.m.</td>
<td>Chair’s Reflections and Preview of Day 2</td>
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<td><strong>W. Craig Vanderwagen</strong>, <em>Workshop Chair</em></td>
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<td>Co-Founder and Director</td>
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<td>East West Protection, LLC</td>
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<td>Networking Reception for Workshop Participants</td>
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### Day 2 - September 6, 2018

#### Session VI  Welcome to Day 2

8:30 a.m.  Welcome and Recap of Day One

**W. Craig Vanderwagen, Workshop Chair**  
Co-Founder and Director  
East West Protection, LLC

#### Session VII  Perspectives from Invited Discussants and Other Sectors

| Objectives |  
| --- | --- |
| ● Reflect on Day 1 discussions with invited discussants and workshop participants  
● Explore lessons learned and identify best practices from other sectors about how they predict, prevent, and respond to shortages |

8:45 a.m.  Panel Discussion V: Reflections from Day 1 with Invited Discussants and Workshop Participants

**Moderator:** W. Craig Vanderwagen, *Workshop Chair*  
Co-Founder and Director  
East West Protection, LLC

**Speakers:**

- **Richard Serino**  
  Former Deputy Administrator  
  Federal Emergency Management Agency  
  Chief, Boston EMS (Ret.)  
  Distinguished Senior Fellow, National Preparedness Leadership Initiative  
  Harvard School of Public Health

- **Linda Rouse O’Neill**  
  Vice President, Government Affairs  
  Healthcare Industry Distributors Association

- **Aisha Liferidge**  
  Associate Professor, Emergency Medicine and Health Policy  
  George Washington University School of Medicine and Health Science  
  American College of Emergency Physicians

- **Cheryl Petersen-Kroeber**  
  Director, Emergency Preparedness and Response  
  Minnesota Department of Health  
  Association of State and Territorial Health Officials
**Christopher Hoff**  
Assistant Director, Community Health Resources  
DuPage County Health Department

**9:30 a.m.**  
Panel Discussion VI: Learning from Other Fields

*Moderator:* Mary Ann Veitch  
Director of Planning  
East West Protection, LLC

*Speakers:*

- **Jarrod Goentzel**  
  Director, Humanitarian Supply Chain Lab  
  Center for Transportation and Logistics  
  Massachusetts Institute of Technology

- **Prashant Yadav**  
  Visiting Scholar, Harvard Medical School  
  Strategy Leader-Supply Chain, Bill & Melinda Gates Foundation

- **Ozlem Ergun**  
  Professor, Mechanical and Industrial Engineering  
  Northwestern University

- **Eric Choy**  
  Chief, Chemical Industry Sector  
  Department of Homeland Security

**10:30 a.m.**  
Audience Q&A

**10:45 a.m.**  
**BREAK**

**Session VIII**  
**Potential Predictive, Prevention, and Response Improvements**

**Objectives**

- Identify existing or novel methods, investments, and incentives to prevent shortages  
- Discuss opportunities and priorities to improve the prediction and prevention of and response to shortages to ensure an ethical and compassionate response  
- Consider best practices for early, effective, and ongoing communication of shortages across stakeholders

**11:00 a.m.**  
Panel Discussion VII: Potential Predictive Improvements

*Moderator:* Erin Fox  
Senior Director, Drug Information and Support Services  
University of Utah
Speakers:

**Julie Swann**  
Department Head and A. Paul Allison Distinguished Professor  
North Carolina State University  
Co-Founder, Center for Health and Humanitarian Systems  
Georgia Tech

**Aleda Roth**  
Burlington Industries Distinguished Professor, Supply Chain Management  
Clemson University

**Dani Peters**  
President  
Magnet Strategy Group

**Amy Kircher**  
Assistant Professor, College of Veterinary Medicine  
University of Minnesota

11:45 a.m.  
Audience Q&A

12:00 p.m.  
**LUNCH**

1:00 p.m.  
Panel Discussion VIII: Potential Prevention Improvements

*Moderator: Sheldon Jacobson*  
Founder Professor of Computer Science  
University of Illinois at Urbana-Champaign

Speakers:

**Rena Conti**  
Associate Professor  
Boston University

**Robin Robinson**  
Deputy Assistant Secretary and Director (Ret.)  
Biomedical Advanced Research and Development Authority  
Department of Health and Human Services

**Anita Patel**  
Senior Advisor  
Pandemic Medical Care and Countermeasures Lead, Influenza Coordination Unit  
Centers for Disease Control and Prevention  
Department of Health and Human Services

**Evren Ozkaya**  
Founder and Chief Executive Officer  
Supply Chain Wizard, LLC
1:45 p.m.  Audience Q&A

2:00 p.m.  BREAK

2:15 p.m.  Panel Discussion IX: Potential Response Improvements

*Moderator:* Karen Remley  
Senior Fellow  
de Beaumont Foundation

*Speakers:*

**Maryann Mazer-Amirshahi**  
Emergency Medicine Physician  
MedStar Washington Hospital Center

**Greg Burel**  
Director, Division of Strategic National Stockpile  
Centers for Disease Control and Prevention  
Department of Health and Human Services

**Laura Wolf**  
Director, Division of Critical Infrastructure Protection  
Office of the Assistant Secretary for Preparedness and Response  
Department of Health and Human Services

**Frank DeLuccia**  
Vice President, Global CMC Regulatory Affairs  
Janssen Research and Development  
Johnson & Johnson

3:00 p.m.  Audience Q&A

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**Robert Kadlec**  
Assistant Secretary for Preparedness and Response  
Department of Health and Human Services

3:45 p.m.  Day 2 Wrap-Up

**W. Craig Vanderwagen,** *Workshop Chair*  
Co-Founder and Director  
East West Protection, LLC

4:00 p.m.  *ADJOURN*