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.

NOTE: Breakfast and lunch will be on your own. Light refreshments will be available at the morning and afternoon breaks. Planning committee members and speakers should see registration staff for additional details.

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
## Session II: Causes and Effects of Medical Product Shortages

**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.

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>9:15 a.m.</td>
<td>Panel Discussion I: Establishing a Shared Understanding of Medical Product Shortages – A Complex Challenge</td>
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<tr>
<td>9:15 a.m.</td>
<td><strong>Moderator:</strong> W. Craig Vanderwagen, <em>Workshop Chair</em></td>
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<td><strong>Speakers:</strong></td>
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<td><strong>Douglas Throckmorton</strong></td>
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<td>9:15 a.m.</td>
<td>Deputy Director for Regulatory Programs</td>
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<td>Center for Drug Evaluation and Research</td>
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<td>Professor, Applied Economics</td>
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<td>Massachusetts Institute of Technology</td>
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<td>Chief Pharmacy Officer</td>
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<td>Cleveland Clinic</td>
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<td><strong>James Callahan</strong></td>
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<td>9:15 a.m.</td>
<td>Senior Director, Global Business Resilience</td>
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<td>Enterprise Risk Management</td>
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<td>10:15 a.m.</td>
<td>Audience Q&amp;A</td>
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<td>10:45 a.m.</td>
<td><strong>BREAK</strong></td>
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<td>11:00 a.m.</td>
<td>Panel Discussion II: Effects of Medical Product Shortages on Patients, Providers, and Systems</td>
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**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

**Steven Krug**  
Head, Pediatric Emergency Medicine  
Professor of Pediatrics, Northwestern University Feinberg School of Medicine  
Chair of the Disaster Preparedness Advisory Council, 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

12:00 p.m.  
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
Eric Goralnick  
Medical Director, Emergency Preparedness and Access Center  
Brigham Health

James Grant  
Chair, Anesthesiology, Beaumont Health  
President, American Society of Anesthesiologists

Elizabeth Jungman  
Director, Public Health  
Pew Charitable Trust

4:00 p.m.  Audience Q&A

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.

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

Sheri Fink  
Author, *Five Days at Memorial*
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<th>Session V</th>
<th>Day 1 Wrap-Up</th>
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<tr>
<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, Workshop Chair</strong></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>5:30 p.m.</td>
<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

<table>
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<th>Objectives</th>
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| • 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:**

- **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
Northeastern 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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<tr>
<th>Session IX</th>
<th>Closing Remarks</th>
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<td>3:15 p.m.</td>
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<td>Robert Kadlec</td>
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|            | 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**