

*The National Academies of*  
SCIENCES • ENGINEERING • MEDICINE

**Committee on Reviewing the Public Health  
Emergency Medical Countermeasures Enterprise  
(PHEMCE)**

**Public Workshop Agenda**

**Thursday, August 19, 2021  
1:30 p.m. – 6:00 p.m. ET**

**Meeting Objectives**

- To hear perspectives on issues related to the PHEMCE mission, ensuring defensible PHEMCE recommendations and enterprise-wide reviews, the integration of external partners and stakeholders into PHEMCE decision-making and activity execution, and best business practices of the industrial base, supply chain, and stockpiling/inventory management for medical countermeasures preparedness.

**Day 1: Thursday, August 19, 2021**

**OPEN SESSION**

1:30 p.m.      **Welcoming Remarks**

GIGI KWIK GRONVALL, *Committee Co-Chair*  
Senior Scholar  
Johns Hopkins Center for Health Security

**SESSION I    What is the Value of the PHEMCE?**

- Objective:
- 1) To hear perspectives on the following issues related to the PHEMCE mission:
    - What should the PHEMCE be required to do? What is the strategic and policy direction of the PHEMCE?
    - What should be the scope of the PHEMCE's mission?
    - How can health equity principles be incorporated into the PHEMCE mission?
    - What is the value that the PHEMCE can and should provide?

- Who should be the primary recipient of the PHEMCE's analysis and advice?
- How should the PHEMCE be organized to meet its mission and have the authority to act?
- How can programs and budgets be aligned and coordinated to support the PHEMCE mission?
- How can PHEMCE be organized to ensure improved transparency and communication and consistent decision making?
- How can PHEMCE be organized to ensure efficient and effective business operations?
- What are lessons learned from the ongoing COVID-19 pandemic?

1:35 p.m. **Re-Envisioned PHEMCE Mission, Operating Structure, and Authorities**

NICOLE LURIE  
U.S. Director  
Coalition for Epidemic Preparedness Innovations (CEPI)  
Former Assistant Secretary for Preparedness and Response

PRABHAVATHI FERNANDES  
Chairperson  
National Biodefense Science Board

2:00 p.m. **Discussion with Committee**

**SESSION II Business Practices for Defensible PHEMCE Recommendations**

- Objective:
- 1) To hear perspectives on the following issues related to the ensuring defensible PHEMCE recommendations and enterprise-wide reviews:
    - How do/should threat assessments and national security considerations factor into PHEMCE decision-making?
    - What best practices/lessons learned from Operation Warp Speed are important to incorporate in a re-envisioned PHEMCE?
    - What best practices related to decision making/investments, quality systems/standards, work flows, processes, and technology are important to incorporate in a re-envisioned PHEMCE?
    - What evidence-based organizational models and processes would better support both long-term policy planning and urgent policy decision needs?
    - What are lessons learned from the ongoing COVID-19 pandemic?

2:30 p.m. **Threat Assessments, National Security Considerations, and Operation Warp Speed**

DANIEL GERSTEIN  
Senior Policy Researcher  
RAND Corporation

ANDREW KILIANSKI  
Senior Director for Emerging Infectious Diseases  
IAVI

TARA O'TOOLE  
Senior Fellow and Executive Vice President  
In-Q-Tel

MATTHEW HEPBURN (*JOINING AT 3 P.M.*)  
Director, COVID Vaccine Development  
HHS-DoD Countermeasures Acceleration Group (formerly Operation Warp Speed)

2:40 p.m.      **Decision-Making, Work Flows, Technology and Processes**

VALERIE KARPLUS  
Associate Professor, Engineering and Public Policy  
Carnegie Mellon University

2:50 p.m.      **Discussion with Committee**

3:15 p.m.      ***30-Minute Break***

### **SESSION III Integration of Partners into the PHEMCE**

- Objective:
- 1) To hear perspectives on the following issues related to the integration of external partners and stakeholders into PHEMCE decision-making and activity execution:
    - How can the PHEMCE be organized to allow greater engagement of external partners and stakeholders and to recognize the spectrum of external performers?
    - How can PHEMCE be organized to ensure improved transparency and communication with partners and stakeholders?
    - How can the PHEMCE better understand its partner relationships?
    - How can health equity principles be incorporated into each step of the medical countermeasures process?
    - From the state and local perspectives, how can the PHEMCE incorporate last-mile issues into upstream decision-making?
    - From the industry perspective, what are best practices related to contracting?
    - From the industry perspective, how does one mitigate risk assumption and its impact on willingness to participate and performance?
    - How the PHEMCE might better influence/impact/understand the industry economy to support government medical countermeasures preparedness mission?

- What are lessons learned from the ongoing COVID-19 pandemic?

3:45 p.m.      **State and Local Perspectives**

KAREN SMITH  
Former State Public Health Officer and Director  
California Department of Public Health

DAVID GRUBER  
Associate Commissioner for Regional and Local Health Operations  
Texas Department of State Health Services

JOHN HICK  
Deputy Chief Medical Director  
Hennepin EMS  
Medical Director for Emergency Preparedness  
Hennepin Healthcare

MARY GREALY  
President  
Healthcare Leadership Council

JAMES LAWLER  
Associate Professor, Department of Internal Medicine  
Director, International Programs and Innovation,  
Global Center for Health Security  
Director, Clinical and Biodefense Research  
University of Nebraska Medical Center

4:00 p.m.      **Business Partners and Industry**

PHYLLIS ARTHUR  
Vice President, Infectious Diseases and Diagnostics Policy  
BIO

MARY KOSINSKI  
Chief of Staff and Deputy Vice President for Science and Regulatory  
Advocacy  
PhRMA

BRUCE ALTEVOGT  
Vice President and Head External Medical Engagement  
Pfizer

EDWARD COX  
Vice President Regulatory Affairs  
Regeneron

PATRICK LUCY  
President and CEO  
Lykan Bioscience

4:15 p.m.      **Discussion with Committee**

<b>SESSION IV Industrial Base, Supply Chain, and Stockpiling</b>
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Objective:      1) To hear perspectives on the following issues related to best business practices of the industrial base, supply chain, and stockpiling/inventory management for medical countermeasures preparedness:

- What best business practices related to the industrial base, supply chain, and inventory management are important to incorporate in a re-envisioned PHEMCE?
- How does the PHEMCE ensure thorough end-to-end medical countermeasures lifecycle consideration?
- How the PHEMCE might better influence/impact/understand the industry economy to support government medical countermeasures preparedness mission?
- What are lessons learned from the ongoing COVID-19 pandemic?

5:00 p.m.      **Industrial Base, Supply Chain, and Stockpiling**

ROBERT HANDFIELD  
Bank of America University Distinguished Professor of Supply Chain Management  
Executive Director, Supply Chain Resource Cooperative  
North Carolina State University

NICOLETTE LOUISSAINT  
Executive Director  
Healthcare Ready

JON MOGFORD  
Chief Operating Officer and Senior Vice President  
Texas A&M Health

5:15 p.m.      **Discussion with Committee**

5:45 p.m.      **Summary of Public Workshop Presentations**

GIGI KWIK GRONVALL, *Committee Co-Chair*  
Senior Scholar

Johns Hopkins Center for Health Security

6:00 p.m. **ADJOURN PUBLIC WORKSHOP**