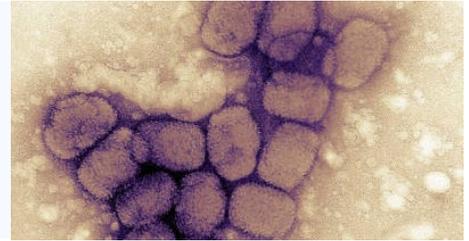


Meeting 3 of the Committee on Current State of Research, Development, and Stockpiling of Smallpox MCMs

Agenda – Thursday, December 14 - Friday, December 15, 2023



THURSDAY, DECEMBER 14, 2023

Purpose

- Hold an open session to hear from different U.S. government partners on key activities relevant to the charge.
- Examine the current state of MCMs for the diagnosis, prevention, and treatment of smallpox, including the continued role of live Variola virus for research and public health purposes.
- Explore how lessons learned from COVID-19 and mpox can inform future preparedness and readiness.
- Examine potential scenarios and strategies that might inform future stockpiling of smallpox MCMs.

SESSION I Day 1 Opening Session

12:00 PM Welcoming Remarks

LARRY GOSTIN, *Committee Chair*

Distinguished University Professor and O'Neill Chair in Global Health Law
Georgetown University and the O'Neill Institute for National and Global Health Law

SESSION II U.S Government Updates

Objectives: Hear briefings from federal stakeholders on current activities for smallpox medical countermeasures.

Guiding Questions:

- What is the current regulatory landscape for smallpox medical countermeasures?
- What is the current research and development landscape for smallpox medical countermeasures?
- What is the current research and development landscape for smallpox medical countermeasures?
- What is the current state of stockpiling of smallpox medical countermeasures?
- What additional areas of research and development could be conducted to improve our MCMs?

NOREEN HYNES, *Moderator, Committee Member*

12:05 PM Food and Drug Administration Panel

NOEL GERALD

Branch Chief for Bacterial Respiratory and Medical Countermeasures
Division of Microbiology Devices
Center for Devices and Radiological Health

Discussion with the Committee

12:20 PM Administration for Strategic Preparedness and Response Panel

STEVE ADAMS

Director, Strategic National Stockpile
ASPR

DANIEL WOLFE

Branch Chief, CBRN Vaccines
BARDA

KAREN MARTINS

Branch Chief, CBRN Antivirals and Antitoxins
BARDA

MARGARET SLOANE

Office of Strategy, Policy, and Requirements
ASPR

Discussion with the Committee

2:00 PM 5-Minute Break

SESSION III Smallpox Medical Countermeasures Landscape

Objectives: 1) Examine current state of MCMs for the prevention, and treatment of smallpox, and 2) Explore how lessons learned from COVID-19 and mpox can inform future preparedness and readiness.

Guiding Questions:

- What is the current research and development landscape for smallpox medical countermeasures?
- How effective are the current MCMs for the diagnosis, prevention, and treatment of smallpox MCMs?
- What additional areas of research and development could be conducted to improve our MCMs?
- How did the mpox outbreak alter assumptions about the efficacy and utility of smallpox MCMs?
- How can the lessons from COVID-19 and mpox inform the US preparedness and readiness posture?

2:05 PM Vaccine Research and Development

RICK KENNEDY, Moderator, Committee Member

PAUL CHAPLIN

Chief Executive Officer
Bavarian Nordic

SETH LEDERMAN

Co-Founder, Chief Executive Officer & Chairman
Tonix

BRETT LEAV

Head, Clinical Development, Public Health Vaccines
Moderna

CHRIS SINCLAIR

Head of Global Preparedness Government Business
Emergent BioSolutions

Discussion with the Committee

3:05 PM Therapeutics Research and Development

INGER DAMON, *Moderator, Committee Member*

CYRUS JAVAN

Medical Officer
Division of AIDS
NIAID

DENNIS HRUBY

Chief Scientific Officer
SIGA

Discussion with Committee

SESSION IV Scenario Planning and MCM Stockpiling Strategies

Objectives: 1) Explore how recent COVID-19 and mpox public health emergencies have altered assumptions about the US preparedness, readiness, and MCMs stockpiling posture for smallpox, and 2) Examine potential scenarios and strategies that might inform future stockpiling of smallpox MCMs.

Guiding Questions:

- How has the mpox outbreak altered our assumption about the availability of smallpox MCMs and the ability to meet potential global demand?
- How do advancements in biotechnology, life sciences research, and converging and enabling technologies alter approaches for scenario planning and stockpiling strategies?
- What options and strategies could be considered to inform the smallpox MCM stockpiling posture?
- How can the lessons from COVID-19 and mpox inform the US preparedness and readiness posture?

3:45 PM Scenario Planning and MCM Stockpiling Strategies

HENRY WILLIS, *Moderator, Committee Member*

NATHANIEL HUPERT

Associate Professor of Population Health Sciences
Cornell University Weill Medical College

CRYSTAL WATSON

Senior Scholar and Associate Professor
Johns Hopkins Center for Health Security

KEVIN YESKEY

Senior Advisor for Emergency Public Health
MDB, Inc.

Discussion with Committee

SESSION V **Wrap-Up and Closing Remarks**

4:25 PM **Summary of Day 1 and Closing Remarks**

LARRY GOSTIN, *Committee Chair*

Distinguished University Professor and O'Neill Chair in Global Health Law
Georgetown University and the O'Neill Institute for National and Global Health Law

4:30 PM **DAY 1 ADJOURNS**

FRIDAY, DECEMBER 15, 2023

Purpose

- Discuss how the COVID-19 pandemic and the mpox multi-country outbreak can inform improvements to smallpox readiness and response.
- Explore how recent COVID-19 and mpox public health emergencies have altered assumptions about the US stockpiling, preparedness, and readiness posture.

SESSION VI **Day 2 Opening Session**

12:30 PM **Welcoming Remarks**

LARRY GOSTIN, *Committee Chair*

Distinguished University Professor and O'Neill Chair in Global Health Law
Georgetown University and the O'Neill Institute for National and Global Health Law

SESSION VII **Synthetic Biology Opportunities and Risks**

Objectives: 1) Hear briefing on advancements in synthetic biology related to smallpox, and 2) Examine the opportunities and risks that these advancements pose to preparedness, readiness, and response capabilities and capacities.

Guiding Questions:

- What is the likelihood for advancements in synthetic biology to develop a poxvirus with pandemic potential?
- How do advancements in synthetic biology alter approaches to preparedness, readiness, and robust public health response to smallpox?
- What opportunities and risks do these advancements pose to preparedness and readiness capabilities and capacities of the United States?

12:35 PM **Synthetic Biology**

DREW ENDY, *Moderator, Committee Member*

CATHRYN MAYES

Senior Biologist
Sandia Laboratories

SESSION VIII **Lessons Learned and Future Considerations for Smallpox Preparedness and Readiness**

Objectives: Explore how recent COVID-19 and mpox public health emergencies have altered assumptions about preparedness, readiness, and MCMs stockpiling posture for smallpox.

Guiding Questions:

- How has the 2022 mpox multi-country outbreak altered our assumption about the availability of smallpox MCMs and the ability to meet potential demand?
- How can the lessons from COVID-19 and mpox inform the US stockpiling, preparedness, and readiness posture?
- What additional areas of research and development could be conducted to improve our MCMs?

12:45 PM **Lessons Learned and Future Considerations**

GEORGES BENJAMIN, *Moderator, Committee Member*

MATTHEW HEPBURN

Chief Medical Officer
JPEO-CBRND

EWA KING

Chief Program Officer
Association of Public Health Laboratories (APHL)

MARCUS PLESCIA

Chief Medical Officer
Association of State and Territorial Health Officials (ASTHO)

1:15 PM **Discussion with the Committee**

SESSION IX **Wrap-Up and Closing Remarks**

1:45 PM **Concluding Remarks**

LARRY GOSTIN, *Committee Chair*

Distinguished University Professor and O'Neill Chair in Global Health Law
Georgetown University and the O'Neill Institute for National and Global Health Law

2:00 PM **Adjourn Open Session**