



HEALTH AND MEDICINE DIVISION

***Ensuring an Effective Public  
Health Emergency Medical  
Countermeasures Enterprise  
(PHEMCE)***

# Committee Membership

- **GIGI GRONVALL (Co-Chair)**, Johns Hopkins Bloomberg School of Public Health
- **ALAN I. LESHNER (Co-Chair)**, American Association for the Advancement of Science
- **JEFFREY BAKER**, National Institute for Innovation in Manufacturing Biopharmaceuticals
- **BRENDAN CARR**, Mount Sinai
- **BARUCH FISCHHOFF**, Carnegie Mellon University
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- **LAUREN SAUER**, University of Nebraska Medical Center
- **JULIE SWANN**, North Carolina State University and University of North Carolina at Chapel Hill
- **W. CRAIG VANDERWAGEN**, East West Protection, LLC
- **PATRICIA J. ZETTLER**, The Ohio State University



# Study Sponsor

## Office of the Assistant Secretary for Preparedness and Response (ASPR)



# Background

- The U.S. MCM enterprise is interconnected, complex, and dynamic.
- It includes public and private entities that (1) develop and manufacture new and existing MCMs, (2) ensure procurement, storage, and distribution of MCMs, and (3) administer, monitor, and evaluate MCMs.
- An effective MCM enterprise requires a mechanism to coordinate and integrate the activities and expertise of the diverse landscape partners and stakeholders involved in these activities.
- The interagency group known as the **PHEMCE is the nation's sole coordinating body responsible for ensuring end-to-end MCM preparedness and response.**



# Charge to the Committee

Make recommendations for a re-envisioned PHEMCE, and provide high-level strategic guidance to ASPR on emerging issues, research, and activities relevant to the PHEMCE programs, goal, and activities.

- Review the effectiveness of existing PHEMCE activities and areas for improvement by assessing available charters, memorandums of understanding, process documents, and public documents
- Provide recommendations on business practices to best incorporate industrial base, supply chain, and stockpiling strategies toward MCM preparedness.
- Provide recommendations on business practices to ensure defensible recommendations, conduct enterprise-wide review of programs and priorities and harmonization across agencies.
- Provide recommendations on the integration of partners in PHEMCE decision making and activity execution.



# Study Methods

- 5 virtual committee meetings held between August and September 2021
- 3 public meetings, including one workshop
- Review of PHEMCE charters, memorandums of understanding, process documents, SNS annual review materials, and public documents



# Delivering on the PHEMCE Mission



# The Committee's Guiding Principles

- **Meeting the Mandate.** PHEMCE is the only coordinating body tasked with all-of-government MCM preparedness and response. It must be empowered with clear and powerful leadership. The metrics for meeting the mandate to reduce mortality, morbidity, inequities, and costs in public health emergencies (PHEs).
- **Transparency.** PHEMCE must make clear decisions that it can defend in compelling recommendations, conveyed to the White House through ASPR and HHS. The metrics for transparency are clear, ethical business practices, reinforcing its public legitimacy.
- **Adaptability.** PHEMCE must evolve as threats, vulnerabilities, and MCM options change. The metrics for adaptability are continuous two-way communication with all PHEMCE partners and with experts in threats, vulnerabilities, and response options.





# Principles for PHEMCE

## 1. Ethics

Trust Building, Fairness, Transparency, Accountability, Stewardship

## 2. Operations

Effectiveness, Adaptability, Systems Approach, Collaboration, Metrics-Driven

## 3. Strategy

## 4. Budget



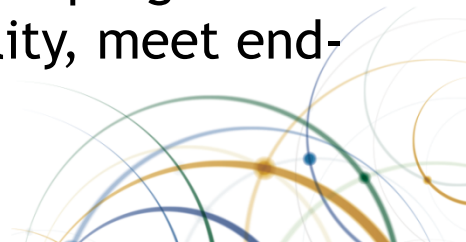
# Ethics

- **Trust Building:** maintaining trust in and across PHEMCE is fundamental to delivering on its mission—working as a reliable partner for internal and external entities.
- **Fairness:** the central ethics principle for a public entity charged with protecting public health is fairness. Fairness here can be, defined as both the outcome of mitigating injustice and inequities and creating procedures likely to promote just outcomes.
- **Transparency:** applies to PHEMCE's practices in a number of key domains, including documentation, effective communication among agency and commercial partners, and security concerns.
- **Accountability:** accountability requires that decisions are evidence based, the rationale is clear, and PHEMCE has coordinated input from federal agencies and other partners to reach collaborative decisions.
- **Stewardship:** as a steward of public funds, PHEMCE must demonstrate responsible management of resources, especially in the scarcity and time pressure that characterize PHEs.



# Operations

- **Effectiveness:** MCMs will need to be successful from conception through production, storage, delivery, and actual use. Effectiveness requires that *evidence-based decisions* lead to desired *impacts*.
- **Adaptability:** PHEMCE's role in preparing for and responding to PHEs requires that it is able to respond nimbly to unexpected and evolving situations.
- **Systems Approach:** considers the life cycle of each MCM asset across the portfolio, including facilities, supply chains, quality management, and workforce, from development to delivery stages, and results in prioritizing across scenarios.
- **Collaboration:** PHEMCE structure and processes should facilitate collaboration at interagency, interagency, and individual staff levels.
- **Metrics-Driven:** metrics are necessary to facilitate quality improvement by benchmarking within and across organizations, monitor progress toward goals, enhance performance, ensure accountability, meet end-user needs, and track impact.



# Strategy

- PHEMCE's strategy should have short-, mid-, and long-term goals that are developed and shared with nonfederal and private-sector partners and stakeholders
- PHEMCE's strategy must include objectives consistent with its mission, directed by status, which describe how it will deliver the right products, at the right time, and to the right population



# Budget

- A life cycle management approach to MCM, with detailed budget plans covering all stages—from requirements setting to distribution—will help to ensure that funds are sufficient for various stages of development
- Joint, complementary budget submissions, with harmonized agency schedules and functions across all PHEMCE agencies, would clarify true costs of MCM activities throughout the life cycle to avoid a product in development encountering a budget gap
- Translating the true costs of end-to-end product development through the SNS Annual Review is essential to support a robust annual budget recommendation to the HHS secretary in order to fully meet preparedness and response goals



# Delivering on the PHEMCE Mission

## **Recommendation 1. REAFFIRM THE PHEMCE MANDATE.**

- The Secretary of HHS and the Assistant Secretary for Preparedness and Response (ASPR) should recognize the critical functions of PHEMCE and reaffirm the PHEMCE mandate as the nation's major coordinating body for all aspects of U.S. MCM preparedness and response programs.

## **Recommendation 2. ADOPT A SYSTEMS APPROACH.**

- PHEMCE should conduct its business under the framework of clear ethical, operational, strategic, and budget goals.

## **Recommendation 3. ENSURE THAT PHEMCE STRATEGIES REFLECT THE PERSPECTIVES OF, AND PROVIDE ACTIONABLE GUIDANCE TO, ITS PARTNERS AND STAKEHOLDERS.**

- PHEMCE should ensure that the perspectives of its partners and stakeholders are incorporated into the PHEMCE Strategy and Implementation Plan and multiyear budget.



# Ensuring that PHEMCE Decisions and Recommendations are Defensible



# Ensuring Defensible PHEMCE Recommendations

In its role, PHEMCE must do the following:

- Coordinate the work of multiple organizations.
- Accommodate personnel changes associated with political events or public health emergencies, including hiring subject matter experts for any and all aspects of emergency operations.
- Shift priorities in response to emerging threats.
- Balance competing interests, including political, efficiency, and effectiveness concerns and the considerations of stakeholders.





# Ensuring Defensible PHEMCE Recommendations

## Priority Setting, Threat Assessments, and Needs Assessments

- PHEMCE priority setting must consider the probabilities and potential impact of threats, as well as the expected return on MCM investments.
- Priorities should be informed by assessments of threats, operational capacities, and MCM multi-functionality, and consider population vulnerabilities, lifecycle costs, and time needed to meet goals and see return on investments.

## Evaluation and Accountability

- Regular monitoring and evaluation could be conducted through periodic performance assessments with key performance indicators (KPIs) representing various outputs in the MCM lifecycle.
- Performance may be assessed through audits, exercises, and after-action reviews.



# Ensuring Defensible PHEMCE Recommendations

## Recommendation 4. USE MEASURABLE OUTCOME METRICS.

- PHEMCE processes should be metrics-driven with meaningful and measurable outcomes that align at interagency and individual agency levels and performance. PHEMCE should agree upon and articulate metrics in the PHEMCE Strategy and Implementation Plan and assess its progress toward strategic goals, outcomes, and processes across component agencies

## Recommendation 5. ESTABLISH AN INTEGRATED AND ACCESSIBLE MCM DATA SYSTEM.

- PHEMCE should establish an integrated and accessible data system to support monitoring, evaluation, and quality management of end-to-end medical countermeasure activities.



# Engaging Nonfederal and Private-sector Partners and Stakeholders to Execute PHEMCE Mission



# External Partners

- PHEMCE cannot achieve its mission objectives without the successful performance, expertise, knowledge, experience, engagement, and support of its partners and stakeholders, who also have a responsibility to actively understand the PHEMCE mission and communicate their needs and preferences.
- PHEMCE must sustain a high-performing network involving non-federal and private-sector partners and stakeholders. This requires transparent communication, internal processes that facilitate sustainable collaborations, and end-to-end engagement through the public health supply chain system.



# Advisory Committee

## **RECOMMENDATION 6. ESTABLISH AN ADVISORY COMMITTEE OF NONFEDERAL AND PRIVATE-SECTOR PARTNERS AND STAKEHOLDERS.**

**PHEMCE should develop and maintain an advisory committee of representative medical countermeasure partners and stakeholders to both garner their expertise and ensure transparency in PHEMCE activities.**

- The advisory committee's input should be sought and considered seriously in all major decisions and actions by PHEMCE regarding the development and delivery of MCMs.
- The advisory committee should balance external partners and threat portfolios to ensure the right combination of threat-specific expertise and other relevant expertise on critical issues like supply chain and stockpiling.
- The advisory committee should help aid PHEMCE in its communication with nonfederal partners, stakeholders, and the public. The meetings should be conducted with appropriate transparency, considering both public discussions and assurances of confidentiality among members, in order to accomplish the intent of this objective.



# Transparency and Two-Way Communication

## **RECOMMENDATION 7. IMPLEMENT TRANSPARENT COMMUNICATION STRATEGIES.**

- PHEMCE should establish mechanisms for transparent communications across the government and with non-federal and private sector partners and stakeholders and the public.

## **RECOMMENDATION 8. ESTABLISH CLEAR AUTHORITIES, ROLES, AND RESPONSIBILITIES FOR EXTERNAL PARTNERSHIPS.**

- PHEMCE should develop, document, and clearly define authority, roles, and responsibilities among federal and nonfederal and private-sector partners and stakeholders, whose perspectives on the status and role of partnerships are vital to the medical countermeasure mission.



# Public Health Supply Chains and Stockpiling

- PHEMCE should create appropriate incentives and commitments for private-sector engagement to promote a resilient and adaptable public health supply chain. These relationships should be designed to reveal vulnerabilities in scaling MCM provisions.

## **RECOMMENDATION 9. CONDUCT A ROOT-CAUSE ASSESSMENT OF COVID-19 U.S. STRATEGIC NATIONAL STOCKPILE (SNS)-SPECIFIC LESSONS LEARNED.**

- PHEMCE should commission an independent, evidence-based, root-cause assessment of lessons learned from COVID-19 and other past public health emergencies specific to the SNS.



# Global Considerations and Synergies

- MCM preparedness and response involves a global network of resources, manufacturing, and distribution. PHEMCE must be engaged at the international level and leverage relationships with international governmental, non-profit, and industry organizations.

## **RECOMMENDATION 10. WORK SYNERGISTICALLY WITH RELEVANT GLOBAL ORGANIZATIONS.**

- PHEMCE should work synergistically with global and other national-level organizations with relevant missions and goals to benefit from their experiences and leverage global expertise and resources as appropriate.





# Legal and Policy Considerations Underlying PHEMCE Operations and Implementation



# Legal and Policy Issues

- The legal and regulatory landscape underpinning PHEMCE has been evolving in response to PHEs such as COVID-19
- PHEMCE agencies must triage legal principles and options to reduce uncertainty, mitigate barriers, and generate solutions to actual or perceived barriers. Regulatory readiness helps assure awareness of legal flexibilities in PHEs among PHEMCE agencies.

## **RECOMMENDATION 11. IDENTIFY, ASSESS, AND RESOLVE THE LEGAL BARRIERS THAT MAY IMPEDE PHEMCE OBJECTIVES.**

- ASPR and the U.S. Department of Health and Human Services' Office of the General Counsel in consultation with outside legal experts should regularly identify, assess, and resolve the perceived or actual legal barriers that may continue to impede PHEMCE objectives.



# Concluding Thoughts

- Given the varied public health threats facing the nation, and the reality that the different federal agencies will continue to work on aspects of MCM preparedness and response, a coordinating body is and will always be needed.
- **PHEMCE plays a critical coordinating role in all-of-government MCM preparedness and response.** The recommendations set forth in this report provide the high-level strategic guidance that ASPR and all federal partners need to ensure PHEMCE fulfills its mission.



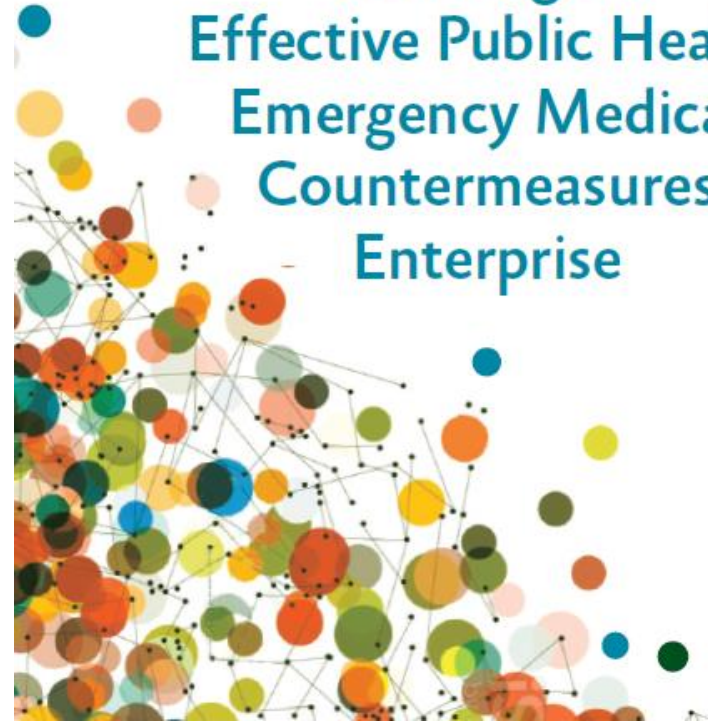
# Public Release

Free PDF of the report and related materials will be made available at:  
<https://www.nationalacademies.org/our-work/committee-on-reviewing-the-public-health-emergency-medical-countermeasures-enterprise-phemce>

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## CONSENSUS STUDY REPORT

### Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise



# Thank You!

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