

Pandemic Preparedness: Strengthening the U.S. Response Framework

Center Forward Basics

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Overview

Pandemic preparedness is at the cornerstone of public health resilience, national security, and economic stability. The COVID-19 pandemic demonstrated the devastating consequences of underfunded public health infrastructure and uncoordinated responses. The legislative framework provided by the **Pandemic and All-Hazards Preparedness Act (PAHPA)** and infrastructure of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) have advanced readiness. But these programs need continued support from Congress and challenges such as **antimicrobial resistance (AMR)**, supply chain vulnerabilities, and inequitable healthcare access persist. Addressing these gaps requires sustained bipartisan efforts and strategic investments.

This Basic outlines critical goals set by relevant federal agencies, provides a baseline understanding of pandemic funding, and summarizes the legislative state of play related to American preparedness.

PAHPA and Pandemic Preparedness Funding

First signed into law in 2006, the Pandemic and All-Hazards Preparedness Act (PAHPA) is the driving authorization policy for enhancing U.S. preparedness and response capabilities. However, a persistent gap exists between the funding authorized under PAHPA and the appropriations allocated by Congress. For 2023–2027, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) estimates a \$79.5 billion funding need, with a projected shortfall of \$46.4 billion if appropriations remain at FY 2023 levels.

Critical gaps include vaccine and therapeutic development funding, advanced manufacturing capabilities, and domestic stockpiling of medical countermeasures. Agencies like the Biomedical Advanced Research and Development Authority (BARDA) and the Strategic National Stockpile (SNS), housed within the Administration for Strategic Preparedness and Response (ASPR) face significant challenges in transitioning medical countermeasures from research to readiness due to insufficient appropriations. ASPR advises the Department of Health and Human Services Secretary on public health and medical emergency preparedness and response, and offers guidance for disaster planning, response, and recovery with specific attention to children, people with disabilities, and other populations. Within PAHPA, advocates for children's health would suggest strengthening pediatric capacity and ensuring the SNS can address pediatric specific needs. Bridging this funding gap ensures the U.S. can respond effectively to future pandemics. The debate regarding the level of appropriations aligned with PAHPA's goals will be critical in the upcoming reauthorization negotiations.

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Key Definitions:

- Pandemic and All-Hazards
 Preparedness Act (PAHPA): U.S.
 federal law enacted in 2006 to improve the nation's public health and medical preparedness
- Anti-Microbial Resistance
 (AMR): The ability of microorganisms to survive exposure to antimicrobial drugs
- Administration for Preparedness and Response (ASPR): ASPR leads the U.S.'s public health preparedness for, response to, and recovery from disasters and public health emergencies
- Medical Countermeasures:
 FDA-regulated products such as drugs, vaccines, biologics, diagnostics, etc. designed to protect against adverse health effects caused by public emergencies
- Strategic National Stockpile:

The Role of Federal Agencies

Federal agencies play a central role in strengthening pandemic preparedness. The Biomedical Advanced Research and Development Authority (BARDA) is pivotal in developing **medical countermeasures (MCMs)** to meet chemical, biological, radiological, and nuclear (CBRN) threats. BARDA has recently transitioned 13 MCMs into the **Strategic National Stockpile (SNS)** and continues to support vaccine development for emerging pathogens. In addition, **Project BioShield** works to accelerate research, development, procurement, and availability of effective MCMs.

The Centers for Disease Control and Prevention (CDC) contributes through real-time outbreak surveillance, data-sharing initiatives, and evidence-based guidelines for healthcare providers. Meanwhile, the National Institutes of Health (NIH) has pioneered the prototype pathogen approach, which focuses on creating vaccines and therapeutics for entire virus families with pandemic potential, enabling faster responses to emerging threats.

Case Study: Mpox

The 2022 Mpox outbreak offered a stark reminder of the need for robust public health preparedness, particularly in early detection, rapid response, and equitable distribution of medical countermeasures. Initially confined to specific regions, Mpox cases quickly spread across continents due to delayed recognition and inadequate public health interventions. Early diagnostic delays hindered the ability to contain the outbreak, as testing infrastructure was not immediately scaled to meet the demands of rapidly increasing cases. Compounding the issue, the limited supply of the JYNNEOS vaccine, a critical tool for high-risk populations, highlighted vulnerabilities in the availability and distribution of medical countermeasures. Many underserved communities and marginalized groups faced inequitable access.

Public communication presented another major challenge. Ambiguities surrounding the modes of transmission and prevention strategies created confusion, which undermined public trust and compliance with health recommendations. However, the response to Mpox also demonstrated the potential of coordinated efforts when federal and state agencies work together. The Strategic National Stockpile played a pivotal role in deploying vaccines to areas of greatest need, and prior investments by the Biomedical Advanced Research and Development Authority (BARDA) enabled rapid manufacturing scale-ups. The lessons learned from the Mpox response emphasize the need for enhanced diagnostic infrastructure, a more robust and readily available vaccine supply, and clear, transparent public communication strategies to manage emerging infectious disease threats effectively.

- The U.S. largest repository of life-saving medical supplies, pharmaceuticals, and equipment
- Project BioShield: Government program to accelerate availability of medical countermeasures
- Multi-drug Resistant Organisms (MDROs): Organisms able to resist multiple classes of antibiotics
- One Health approach: A
 collaborative effort to improve the
 health of people, animals, and the
 environment by recognizing their
 interconnectedness
- Active Pharmaceutical Ingredients (APIs): The biologically active component in a pharmaceutical drug

Key Statistics:

- In the U.S., more than 2.8 million drug-resistant infections occur annually, causing more than 35,000 death
- Hospital readmissions for patients with drug-resistant infections are 49.2% higher compared to those with susceptible infections
- Some estimates suggest AMR could result in \$34 billion in additional costs annually to the U.S
- More than 80% of critical APIs used in U.S pharmaceuticals are sourced from foreign suppliers
- The World Bank estimates pandemic-related disruptions will cost \$100 trillion globally by 2050
- Only 47% of hospitals have a disaster plan that includes pediatric patients

Antimicrobial Resistance: A Growing Threat

Antimicrobial resistance (AMR), the ability of microorganisms to survive exposure to antimicrobial drugs, remains among the most significant threats to public health and global pandemic preparedness. Resistant pathogens undermine routine medical treatments, such as surgeries, dialysis, and chemotherapy, while increasing healthcare costs and mortality rates. The growing prevalence of **multidrug-resistant organisms (MDROs)** further exacerbates the crisis.

Factors driving AMR could include overuse and misuse of antibiotics and lack of rapid diagnosis. Additionally, even with proper oversight, antibiotics to animals, humans, and agriculture can contribute to AMR, but further research would help us better understand how all of these organisms are interconnected in their contribution to AMR. Furthermore, global travel and trade accelerate the spread of resistant pathogens, underscoring the need for coordinated international efforts. Some say addressing AMR challenges requires expanding antimicrobial stewardship programs, incentivizing the development of novel antibiotics, and fostering **One Health approaches** that integrate human, animal, and environmental health strategies. Without robust investments and global collaboration, AMR will likely continue undermining public health efforts and exacerbating the next pandemic.

Domestic Supply Chain Resilience

The COVID-19 pandemic exposed significant vulnerabilities in the United States healthcare supply chain, underscoring the dangers of heavy reliance on foreign manufacturers for critical goods. Delays and shortages of personal protective equipment (PPE), ventilators, and **active pharmaceutical ingredients (APIs)** severely hampered the nation's ability to respond quickly and equitably. These disruptions disproportionately affected underserved communities, exacerbating existing disparities in access to care during public health emergencies. To address these weaknesses, policymakers are shifting their focus toward building resilience within domestic supply chains. While geographic diversity is an important factor in the global supply chain, overdependence on product from other nations can create a strategic vulnerability for the United States, especially during disruptions such as disaster or disease outbreak,

One such strategy incentivizes domestic manufacturing to create redundancies that reduce dependence on foreign suppliers. Initiatives like "America is an API Powerhouse" aim to bolster U.S.-based production of APIs and other essential medical supplies, creating a more self-sufficient and secure supply chain. Public-private partnerships are another critical component, leveraging the expertise and resources of private-sector entities to expand advanced manufacturing capabilities. Additionally, improved data-sharing and coordination mechanisms are essential to address supply chain disruptions proactively across sectors.. Real-time monitoring and data-driven decision-making can facilitate more efficient resource allocation during crises, ensuring materials are available where needed most. A drug or supply shortage is particularly challenging in pediatric health care as drugs and supplies intended for children come from a limited number of manufacturers.

Investing in domestic manufacturing, operational resilience, and pediatric product availability is not merely a logistical necessity but a national security imperative. Strengthening the supply chain will enhance the nation's ability to respond effectively to future public health emergencies, minimize disruptions, and protect the health and well-being of all Americans.

Legislative Outlook and Conclusion:

The pending reauthorization of PAHPA is a critical opportunity to address funding gaps and improve collaboration between federal and state entities. Advocates emphasize the importance of increasing resources for medical countermeasure research, enhancing stockpiling capabilities, and fostering public-private partnerships. Supporters of incentivizing private sector involvement often point to strategies such as tax credits, accelerated regulatory pathways, and the importance of both supply-side and demand-side incentives to encourage domestic manufacturing, innovation, and ensuring rapid production capabilities during emergencies. International cooperation is frequently highlighted as essential, with initiatives like the National Antimicrobial Resistance Monitoring System (NARMS) serving as examples of collaborative efforts to enable data sharing, detect emerging threats, and coordinate responses on a global scale.

Many stakeholders in the United States supply chain regard pandemic preparedness as a public health and national security priority. Proponents argue addressing systemic vulnerabilities requires strategic investments, innovation, and careful planning. Discussions around reauthorizing legislation like PAHPA often include expanding the roles of federal agencies such as BARDA, the CDC, and NIH to build a more robust framework for responding to future crises. Observers point to lessons learned from COVID-19 and other public health emergencies as valuable insights for strengthening preparedness. Efforts informed by collaboration and innovation are commonly seen as essential to mitigating future risks and ensuring resilience.

Link to Additional Resources

- Administration for Strategic Preparedness & Response: Strategy and Implementation Plan 2024
- Administration for Strategic Preparedness & Response: Multiyear Budget
- American Association of Medical Colleges: <u>Lessons from COVID</u>
- AMR.Solutions: <u>Fact Sheet</u>
- Biomérieux: The Antimicrobial Resistance Crisis
- Center for Global Development: Forecasting the Fallout from AMR
- Center for Strategic and International Studies: <u>Bipartisan Alliance for Global Health Security</u>
- Children's Hospital Association: <u>Blueprint for Pediatric-Specific Readiness</u>
- Children's Hospital Association: <u>Principles for a Child-appropriate Disaster and Pandemic Response System</u>
- Coalition to STOP Flu: 2023-2024 Influenza Season Outcomes and Policy Recommendations
- Duke Margolis Institute for Health Policy: Building a Resilient and Secure Pharmaceutical Supply Chain
- Food and Drug Administration: Animal & Veterinary
- Food and Drug Administration: Annual Summary of Sales and Distribution of Antibiotics
- Healthcare Distribution Alliance: <u>Supply Chain Resilience Report</u>
- Healthcare Distribution Alliance: <u>Pandemic and All-Hazards Preparedness Act Reauthorization Background and</u>
 <u>Opportunities to Enhance Resilience</u>
- Healthcare Distribution Alliance: PAHPA Reauthorization High-Level Summary and Recommendations
- Pediatric Disaster Centers of Excellence: <u>Home Page</u>
- Pediatric Pandemic Network: <u>Home Page</u>
- PhRMA: Antimicrobial Resistance Fact Sheet
- PhRMA: <u>The AMR Ecosystem</u>
- PhRMA: Biopharmaceutical Supply Chains
- PhRMA: <u>Lessons Learned and Fighting Future Pandemics</u>
- PhRMA: PDUFA Fact Sheet
- World Health Organization: <u>Antibacterial Pipeline Trends</u>