

## Pandemic and All-Hazards Preparedness Act Reauthorization: Background and Opportunities to Enhance Resilience

### Introduction

In 2006, Congress passed the Pandemic and All-Hazards Preparedness Act ([PAHPA](#)) to help the nation prepare and respond to any hazard that threatens public health. The COVID-19 pandemic highlighted the importance and role of federal, state, local and private stakeholders' actions in maintaining a resilient supply chain when responding to a public health emergency (PHE). PAHPA is a practical piece of legislation that the public and private sectors rely on to prepare and respond to events impacting public health. The goal of PAHPA is to clarify who holds the responsibility during an event impacting public health.

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors, who serve as the vital link between pharmaceutical manufacturers and dispensers. HDA's distributor members [demonstrated their capabilities](#) during the COVID-19 pandemic to support the pandemic response by partnering with the federal government to distribute COVID-19 vaccines and therapeutics. Furthermore, HDA and its members believe the reauthorization of PAHPA is critical to ensure public-private coordination runs seamlessly during a PHE. HDA stands ready to provide guidance and expertise to Congress on this legislation.



### PAHPA Background

After the enactment of the Public Health Improvement Act in 2000, PAHPA became the [second reauthorization](#) of federal programs designed to improve the nation's readiness for events impacting public health. PAHPA was preceded by the Public Health Improvement Act, which established the Public Health Emergency Fund (PHEF) and provided the secretary of the Department of Health and Human Services (HHS) with the authority to respond to a PHE. Amid growing concerns about threats to public safety and health caused by emerging infectious diseases and global terrorism, the original [PAHPA](#) passed Congress by unanimous consent and was signed into law by President George W. Bush in December 2006.

Through the enactment of PAHPA, the federal government achieved the following objectives:

- Authorized dedicated funding to improve bioterrorism and other PHE preparedness and response activities;
- Formed the Biomedical Advanced Research and Development Authority ([BARDA](#)) within the HHS. BARDA focuses on advanced research and developing medical countermeasures for use during a crisis like bioterrorism or a pandemic;

- Established the Office of the Assistant Secretary for Preparedness and Response (ASPR);<sup>1</sup>
- Moved the National Disaster Medical System from the Department of Homeland Security (DHS) to HHS;
- Created the National Biodefense Science Board (NBSB);
- Authorized \$1 billion in grants to state and local health departments for public health and medical preparedness;
- Required a National Health Security Strategy to be developed every four years; and,
- Created an almost real-time nationwide public health situational awareness network.

PAHPA was reauthorized in [2013](#) as the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA). Through the enactment of PAHPRA, the federal government achieved the following:

- Reauthorized essential programs, like Project BioShield<sup>2</sup>, to protect the nation against all hazards and chemical, biological, radiological or nuclear (CBRN) attacks;
- Authorized funding for the temporary reassignment of public health professionals for emergency response;
- Authorized manufacturers to work with the Food and Drug Administration (FDA) to create regulatory management plans; and,
- Required a medical countermeasures strategy, implementation plan and five-year budget.

PAHPA was reauthorized in [2019](#) as the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPIA). Through the enactment of PAHPIA, the federal government achieved the following:

- Approved previous PAHPA-related programs and established new ones;
- Established the Public Health Countermeasures Enterprise (PHEMCE) coordinating body;
- Expanded authorization for the HHS public emergency response fund, to allow its use before a formal PHE declaration;
- Required ASPR to create guidelines for a regional healthcare response system and authorized a seven-billion-dollar budget for Project BioShield to purchase medical countermeasures for national security threats; and,
- Authorized \$7 billion in funding over 10 years for Project BioShield to purchase medical countermeasures.



The COVID-19 pandemic demonstrated the necessity of federal oversight and implementation of national preparedness systems and strategies. Congress is expected to [reauthorize PAHPA](#) in the first session of the 118th Congress.

<sup>1</sup> ASPR is now the Administration for Strategic Preparedness and Response.

<sup>2</sup> Project BioShield was originally proposed by President Bush in 2003 and it was enacted into law in 2004 from the Project BioShield Act.

## PREVENT Pandemics Act and Its Relation to PAHPA

After the COVID-19 pandemic, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act ([PREVENT](#)) was approved by Congress and signed into law at the end of 2022. PREVENT complements PAHPA's preparedness and response work by better preparing the U.S. for future pandemics.

PREVENT aims to:

- Strengthen the supply chain and government stockpiles of critical medical countermeasures;
- Improve coordination and strategy amongst public health agencies; and,
- Fortify America's public health and medical preparedness and response systems.

Key accomplishments of PREVENT include the creation of the White House Office of Pandemic Preparedness and Response, the authorization of the Strategic National Stockpile (SNS) Vendor Managed Inventory (VMI) and warm base capacity and the PHEF for initial deployment and distribution of SNS products. PREVENT expands ASPR's duties to conduct SNS operational drills and exercises and coordination to support medical product and supply chain planning.

HDA and its distributor members [supported PREVENT](#) and saw it as an opportunity to build a more robust public health system and increase supply chain resilience. As Congress moves forward on the PAHPA reauthorization, HDA and its members believe there is bipartisan desire to build off the policies and changes from PREVENT to ensure seamless public-private coordination for all-hazards response and preparedness.

## The Elevated Role of ASPR in Responding to Events

Previously known as the Office of the Assistant Secretary for Preparedness and Response, ASPR was created in 2006 under PAHPA. ASPR has [always held the following operational responsibilities](#), which include the National Disaster Medical System (NDMS), BARDA and the Medical Reserve Corps. Additionally, in 2018, the SNS began operating as part of ASPR. The HHS Coordination Operations and Response Element ([H-CORE](#)) was also established as part of ASPR in early 2022.

In 2022, ASPR was renamed the Administration for Strategic Preparedness and Response. ASPR has undergone many [changes](#), including moving from a division to an operation within HHS. HDA welcomes this evolution and its members believe the expansion of ASPR and its critical programs can improve coordination within the healthcare supply chain on matters of preparedness and response. Indeed, ASPR's elevation to a standalone agency within HHS puts it on par with agencies like the Centers for Disease Control and Prevention (CDC) and FDA.

ASPR's previous and current purpose is to assist the United States in preparing for, responding to and recovering from public health emergencies and disasters. ASPR accomplishes that mission by preparing for future events, managing event response and recovery coordination, improving and leveraging partnerships, and ensuring workforce readiness. Critical programs of ASPR include the Industrial Base Management and Supply Chain Program Office ([IBMSC](#)), [SNS](#), [H-CORE](#) and [BARDA](#).

As noted earlier, PREVENT expanded ASPR's duties, clarifying its scope and role in guiding preparedness and responding to future pandemics. The following provisions in PREVENT relate to the healthcare supply chain:

- Allow the use of the PHEF for the initial deployment and distribution of SNS products (Section 2103);
- Add duties to ASPR, including responsibility for conducting SNS operational drills and exercises, coordinating within HHS to support medical product and supply chain planning for surges in supply needs, and monitoring situational awareness related to supply availability (Section 2103);
- Create the new White House Office of Pandemic Preparedness and Response Policy (Section 2104);
- Authorize the SNS to support VMI and warm base capacity (Section 2405); and,
- Provide a new grant program for state strategic stockpiles (Section 2409).

As PAHPA seeks to address preparedness and response for future events impacting public health, it is important to consider the recent changes to ASPR from PREVENT and the elevation of ASPR.

## Opportunities To Enhance Supply Chain Resilience in the Reauthorization of PAHPA

### Clarify Coordination and Communication Hierarchy and Responsibilities

HDA and its members recommend using PAHPA to review how coordination and response roles align with other parts of the federal government. Specifically, distributors suggest that PAHPA address differences in the coordination and supply roles for those events where the lead federal agency may be different from HHS (e.g., a cyber event, pandemic or natural hazard). The newly created White House Office of Pandemic Preparedness Policy is also expected to serve as the federal government's principal advisor for pandemic preparedness and response. PAHPA must further clarify where the primary responsibility for partnering and coordinating with the private sector supply chain lies. Clear role delineation is essential to avoid confusion and multiple reporting channels and to ensure the timely delivery of medical products during an event.



Photo Credit: McKesson Corporation

The pending reauthorization of PAHPA is an opportunity to clarify further how ASPR's authorities interact with other federal agencies and private-sector partners to guide preparedness and response to future events that impact public health. The current role and scope of ASPR include information sharing with stakeholders, coordination of other federal partners, managing public-private partnerships (PPPs), and planning for medical surges and situational awareness related to supply availability. ASPR's authorities, scope and role has changed since the 2019 PAHPA reauthorization. Accordingly, HDA and its members recognize ASPR will lead in healthcare preparedness and response, and as such, expect partnerships for supply chain coordination will continue.

### Form a Healthcare Distribution Supply Chain Advisory Group

Healthcare distributors were vital partners to the federal government during the COVID-19 pandemic. Distributors collaborated closely with the Federal Emergency Management Agency (FEMA), the White House and the Department of Health and Human Services (HHS). Through these partnerships, distributors shared information on supply chain capabilities, coordinated with the Supply Chain Control Tower (SCCT) to provide information on product availability for crucial items and managed the distribution of COVID-19 vaccines and therapeutics. During the COVID-19 pandemic, the federal government demonstrated a willingness to work with distributors to understand the healthcare supply chain and discern what actions could enable the flow of medical products in a disaster context.

Distributors seek the opportunity to expand the partnerships developed with the federal government during the COVID-19 pandemic for future events. To this end, HDA supports the creation of a Healthcare Distributor Supply Chain Advisory Group (HDAG). The HDAG should comprise ASPR, PHEMCE, healthcare distributors and FEMA. Moreover, the HDAG would aim to examine possible methods to grow PPPs for future preparedness and response efforts for events that impact public health.

The HDAG could consider ways to convene federal agencies and distributors to plan for future emergencies, maintain updated plans for urgent medical product and pharmaceutical distribution and support relationships that grew during the COVID-19 response. The HDAG would leverage the existing distribution network with advanced planning. Additionally, longstanding PPPs would reduce risk, expedite a response and build resiliency. HDA and its members recommend including the HDAG in PAHPA.

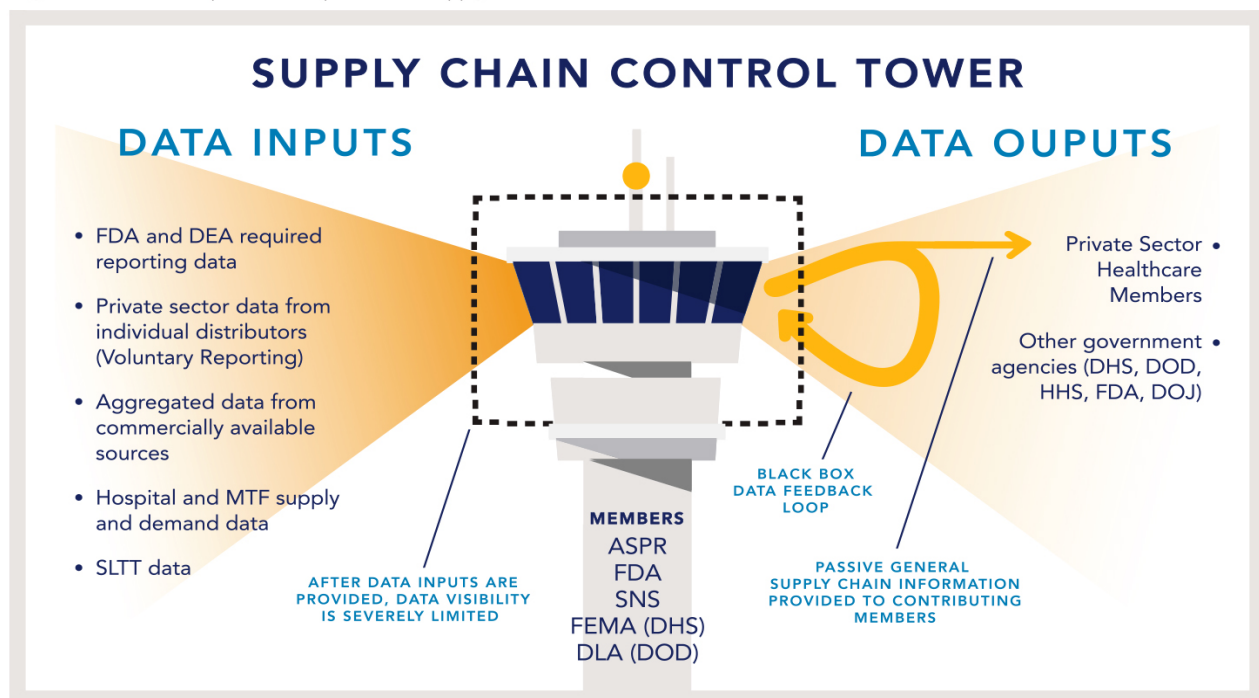
The inclusion of the HDAG will grow existing partnerships developed during the COVID-19 pandemic for public-private coordination for preparedness and response to future events. Without the HDAG, there is a risk that the public and private sectors will lose the relationships and knowledge of how to successfully partner to respond to events.

### Improve the SCCT

During the COVID-19 pandemic, the federal government established data and information-sharing mechanisms through the HHS [Supply Chain Risk Management \(SCRM\) Program](#). The SCRM aims to identify vulnerabilities, prevent and detect disruptions and develop mitigation strategies. One key SCRM component is the [SCCT](#), a PPP between industry, HHS and other federal agencies to facilitate end-to-end supply chain visibility and inform government decision-making.

Healthcare supply chain stakeholders, including distributors, voluntarily participate in the SCCT. The SCCT provides visibility on manufacturer capabilities, distribution flows, point-of-care consumption and end-to-end inventory levels. It also provides insights on demand forecasting, scenario modeling and demand-supply gap prioritization. Finally, the SCCT informs response on capacity planning and acquisition strategy, targeted distribution and strategy and policy refinement. During the COVID-19 pandemic, the SCCT provided [data illumination](#) in the healthcare supply chain during a unique, crisis-level environment.

Figure 2: Perceived inputs and outputs of the Supply Chain Control Tower based on interviews



<b>FDA</b>	U.S. Food and Drug Administration	<b>FEMA</b>	Federal Emergency Management Agency
<b>DEA</b>	Drug Enforcement Agency	<b>DHS</b>	Department of Homeland Security
<b>MTF</b>	Multi-Time Frame	<b>DLA</b>	Defense Logistics Agency
<b>SLTT</b>	State, Local, Tribal, and Territorial Governments	<b>DOD</b>	Department of Defense
<b>ASPR</b>	Administration for Strategic Preparedness and Response	<b>HHS</b>	U.S. Department of Health and Human Services
<b>SNS</b>	Strategic National Stockpile	<b>DOJ</b>	U.S. Department of Justice

The end of the pandemic and public health emergencies presents an opportunity to clarify and strengthen the role of the SCCT moving forward. First, the SCCT must have concrete parameters to minimize confusion around its use during steady-state versus adverse-event conditions. Second, the SCCT data structure can be improved to maximize its use. While the current structure of the SCCT is beneficial, it does not facilitate two-way communication, which leaves private-sector entities without access to critical data. Furthermore, the data collected do not include information from direct care providers, API producers, managed care organizations or non-hospital healthcare facilities. Because of these gaps, SCCT data do not provide insight into the demand surge for healthcare products. HDA recognizes the need for data collection coordination during a public health emergency; however, coordination requires clear parameters moving forward.

The SCCT depends on voluntary participation from healthcare distributors and other private partners. HHS wants to keep the SCCT to support supply chain resiliency and prepare for future events impacting public health. To incentivize continued private sector involvement in the SCCT, and especially during the next event impacting public health, ASPR should consider the following recommendations:

- Establish a clear definition and parameters for the use of the SCCT;
- Establish that the SCCT is to be fully operational only during a public health emergency and is kept at a “warm” posture during steady-state times;
- Consider antitrust sensitivities regarding the use of data submitted to the SCCT by private companies;
- Establish and maintain cybersecurity protections; and,
- Prohibit using data submitted that affect the commercial market, like reallocating distributor product inventory.

### **Avoid Drug Shortages and Ensure the Supply of Essential Medicines**

About [90 percent of drugs dispensed](#) are generic prescription drugs, and somewhere between 20 to 40 percent of generic drugs have gone into shortage at some point. During the COVID-19 pandemic, policymakers and the public were attuned to the vulnerabilities within the healthcare supply chain. For example, the albuterol inhaler, an essential treatment for COVID-19 and asthma, is in [shortage](#) because of increased demand from COVID-19, RSV and Akorn Pharmaceuticals’ closure. This incident and other recent high-profile drug shortages caught the attention of policymakers and highlighted the need for collaboration between the public and private sectors to prevent supply chain disruptions and drug shortages during both steady-state times and events that threaten public health.

To prepare and respond to disruptions, FDA and HHS should work with distributors and other supply chain stakeholders to develop a drug shortage “early warning system” to detect potential demand surges that may create a significant product description or a drug shortage. The early warning system would complement the SCCT and allow it to remain at a warm posture during steady-state times. Distributors have the capacity to [monitor demand spikes or changes](#) in product availability in real-time to meet patient needs. Healthcare supply chain stakeholders recognize disruptions will occur within the supply chain and an early warning system will minimize disruptions.

Several proposals have been made at the federal level to ensure access to “essential medicines” and avoid drug shortages. Rep. Buddy Carter (R-Ga.) and Rep. Lisa Blunt Rochester (D-Del.) introduced [H.R. 405](#), the Essential Medicines Strategic Stockpile Act of 2023 (118th Congress). This bipartisan legislation seeks to amend the Public Health Service Act to establish a pilot program that creates a six-month stockpile of generic drugs at risk of shortage. Under this proposal, the HHS secretary will determine the 50 generic drugs chosen to be in the stockpile. HDA and its members recommend that H.R. 405 be included in the PAHPA reauthorization legislation. Additionally, HDA recommends HHS and ASPR establish the list of the 50 generic drugs essential to maintaining public health.

HDA is also aware of the efforts to consider expanding the public health industrial base. The ASPR Industrial Base Expansion office is a helpful coordination point to review linkages in the supply chain and guide

strategic investments in onshoring and nearshoring critical products. HDA and its members recognize the importance of diversifying the supply chain to ensure resilience and national security, especially for times of crisis. This effort should focus on diversifying crucial supply chains rather than diverting them.

Significant cost barriers are involved in expanding domestic production capacity and maintaining additional production and transportation capacity to respond to potential emergencies. Some of those barriers include the United States' [overseas dependence on raw materials and API](#), which make domestic production of key source materials (KSMs) difficult. As a result, distributors encourage financial incentives enabling supply chain organizations to support these efforts.

Additionally, it is important to note that distributor capabilities, which include an extensive network of distribution and warehousing facilities across the United States, will remain able to deliver FDA approved products intended for the United States regardless of the country of origin.

## Strengthen the SNS

The SNS is critical to protecting public health during events. Established in 1999, the SNS is the federal government's largest repository of emergency medical countermeasures. The role of the SNS is to acquire and deploy medical countermeasures during public health emergencies needed by states, tribal nations, territories and large metropolitan areas.



Currently, the SNS holds about \$13 billion in revenue to respond to chemical, biological, radiological and CBRN threats. The SNS and its commercial partnerships were critical for delivering medical countermeasures for the COVID-19 pandemic, the Mpox outbreak and the surge of RSV and the flu. Potential threats the SNS holds medical countermeasures for include smallpox, anthrax, botulism, plague, emerging infectious diseases and radiation.

HDA and its members have been longtime partners of the SNS and support further strengthening the SNS. The SNS relies on the commercial distribution system to manage and deliver medical countermeasures for events. The SNS is important in the United States' ability to prepare and respond to events because it holds medical countermeasures that do not have a commercial market, like the smallpox vaccine.

The SNS includes commercially available products and partners with distributors to hold sufficient quantities. To support the critical mission of

the SNS, the SNS should receive a funding authorization that, at a minimum, maintains the Fiscal Year 2023 appropriated funding level. The SNS manages the planning, stockpiling and movement of medical countermeasures needed to protect Americans from a range of events, and this requires a more robust threat planning process. Without appropriate funding levels, the SNS cannot procure medical countermeasures from BARDA, leaving the United States underprepared for events impacting public health.

Section 2405 of PREVENT authorized the SNS to support VMI and warm base capacity by including manufacturers or distributors via a contract or cooperative agreement. Rating the commercial supply chain's capabilities with the SNS will strengthen supply chain resilience and mitigate risk for future events impacting public health. Distributors were pleased to see that provision but believe that PAHPA must further align the VMI strategy with continued investment and a robust threat analysis process to help enhance readiness.

HDA and its members welcome further expansion of the VMI strategy with distributors to ensure that products needed for a range of hazards can be available through the stockpile at levels necessary to provide a buffer for the first six to eight weeks of a high-risk event. Specific medical countermeasures for events that impact public health are already circulating within the commercial market, like Tamiflu®. HDA and its members recommend establishing a process to determine what products should be part of VMI. We also recommend establishing a method to determine how best to conduct ongoing threat assessment activities outside of annual exercises and testing. Currently, the SNS cannot hold all medical countermeasures needed to serve every American during an event impacting public health. Distributor partnerships with the SNS expand the SNS response capabilities during these types of events. VMI significantly reduces the risk of products in the SNS expiring because healthcare distributors rotate and cycle stockpile inventory through commercial channels.

Section 2406 of PREVENT allows for the reimbursement of certain supplies by authorizing the selling of excess products from the SNS to other entities when that product no longer meets the needs of the SNS. PAHPA can further strengthen this provision by including VMI solutions that allow a product to be commercially available before the SNS procures the product. PAHPA should also provide parameters for when the SNS procures a product and there is an excess of that product in the SNS. The parameters should establish the coordination of how to transfer the excess of that product to the commercial market. Those parameters will act as guardrails to prevent the dumping of excess product volumes from the SNS into the commercial market, which can disrupt the commercial market and other government programs.

The SNS can bolster its readiness for future events by ensuring its technology systems connect with private sector partners. PAHPA should require the SNS to work with all United States-based healthcare distributors' voluntary partners on developing and maintaining IT connectivity. There is an issue with the HHS/SNS systems connecting and maintaining interoperability with private sector partners. The SNS technology systems should be evaluated annually through testing and exercises with the private sector to ensure readiness for events. Connectivity with the HHS/SNS technology systems will ensure that private partners can implement changes to achieve and maintain interoperability with the HHS/SNS systems.

HDA and its members strongly support policies that will strengthen the SNS. Private-sector partnerships with the SNS — notably distributor partnerships — allow the SNS to enhance its capabilities to serve all Americans during an event. A modernized SNS that includes consistent and appropriate funding levels, an expanded VMI strategy, strategies to prevent dumping SNS products and IT interoperability with the private sector will improve the SNS capabilities to respond to CBRN and other public health threats.

### **Generate Government Accountability Office (GAO) Reports**

GAO reports provide Congress, federal agencies, private stakeholders and the public with timely, fact-based, non-partisan information that can improve government operations. HDA and its members are interested in data sources and the use of the Defense Production Act (DPA).

HDA recommends that PAHPA include provisions that require the GAO to report on the existing healthcare supply chain data and information flows from the private sector to the federal government. Private sector real-time data reporting is onerous, sometimes involves trade secrets and does not guarantee increased coordination or improved resilience. A GAO report would provide both the public and private sectors with





a clearer picture of existing tools that can be better leveraged by federal partners for steady-state visibility into the healthcare supply chain and provide early warning of potential disruptions rather than creating new ad-hoc reporting channels for public health emergencies. A deeper understanding of how data and information flow will allow both the public and private sectors to better prepare and respond to events that impact public health.

The DPA was widely used during the COVID-19 pandemic because it provides presidential authorities to expedite and expand the supply of materials and services from the United States' industrial base to promote national defense. The president can direct private companies to prioritize orders from the federal government, primarily via executive order.

During the COVID-19 pandemic, the DPA was used to secure components needed and expand medical countermeasures. The DPA is in effect until the John S. McCain National Defense Authorization Act of 2019 [expires in 2025](#). To understand the past and future uses of the DPA, HDA and its members recommend the creation of a GAO report on the use of the DPA to address the healthcare supply chain during catastrophic events. Public and private stakeholders benefit from a better understanding of the DPA and its future uses.

### **Partnerships With the PHEMCE**

The PHEMCE is part of the United States' preparedness efforts against chemical, biological, radiological, nuclear and emerging infectious disease threats. It improves the availability of medical countermeasures and PPE during public health events, including large-scale disasters or disease outbreaks. PHEMCE is a longstanding PPP and has established effective programs, goals and medical safeguards on matters of health security and biodefense.

PHEMCE has [specifically highlighted](#) the importance of coordinating with the pharmaceutical sector in the development of medical countermeasures. To bolster the work of PHEMCE, HDA recommends that the PHEMCE solicits input from distributors on strategy development for medical countermeasure deployment, distribution and dispensing. Including distributors in preparedness and response planning allows medical distributors to employ their expertise in preparing to respond to a public health event.

### **Include Distributors in Project BioShield**

[Project BioShield](#) was created in 2004 to become part of a larger strategy against CBRN threats. Project BioShield researches, manufactures and facilitates the development of "next-generation" medical countermeasures for CBRN threats. It also allows the government to buy improved medical countermeasures, like vaccines or drugs, for potential CBRN threats.

To better prepare the nation against CBRN threats, Project BioShield should expand its focus from research and manufacturing to include storing, handling and managing finished medical countermeasures. To this point, Project BioShield can be strengthened if distributors are used as partners to hold and, when appropriate, distribute medical countermeasures during an event that impacts public health.

### **Address Cybersecurity Threats**

For the United States to be prepared for threats impacting public health and all-hazard events, it is critical to address cybersecurity. The healthcare supply chain is vital during both steady-state and crisis conditions because it manufactures, distributes and dispenses healthcare products.

HDA and its members recognize cybersecurity threats are a part of all-hazards preparedness and response because of the potential disruptions cyberattacks have on the healthcare supply chain. Notably, healthcare stakeholders like [NextGen Healthcare](#) have recently been victims of ransomware attacks. Distributors are at a higher risk of becoming cyberattack victims because of their frequent interactions with several different companies and systems. A large-scale attack against any healthcare supply chain stakeholder has the potential to cause disruptions and limit availability to medical products. To better understand and respond to emerging cybersecurity threats, HDA recommends that PAHPA requires a GAO report that outlines the full capabilities and limitations potential cybersecurity threats pose to the healthcare supply chain.

HDA also recommends PAHPA includes language to expand the use of the PHEF funding to address cybersecurity. The expanded PHEF funding should be available to private healthcare supply chain stakeholders who suffer a cyberattack during an event that impacts public health.

## HDA Policy Recommendations for PAHPA Reauthorization

### Administration for Strategic Preparedness and Response

- [Supply Chain Control Tower](#) (SCCT) should be:
  - Only fully operational during a public health emergency (PHE). The SCCT should stay at a warm posture between events, which includes the ability to scale up for events.
  - Be mindful of antitrust considerations regarding the use of data submitted to it by private companies.
  - Be required to maintain cybersecurity protections.
  - Include private partners in annual testing and exercises.
- [Strategic National Stockpile](#) (SNS):
  - To support the SNS program and its partnerships, the SNS should receive a funding authorization that, at a minimum, maintains the Fiscal Year 2023 appropriated funding level.
  - PAHPA should establish a process to determine what products should be part of Vendor Managed Inventory (VMI). Also, PAHPA should implement a process to determine how best to conduct ongoing threat assessment activities outside annual exercises and testing.
  - PAHPA should require the SNS to work with all U.S.-based healthcare distributors' voluntary partners on developing and maintaining IT connectivity.
  - The SNS should review its management and reimbursement practices for medical products with distributors before procuring certain supplies and in cases where there is a product excess.
- Biomedical Advanced Research and Development Authority (BARDA):
  - The federal government should maintain and expand loan, grant, direct investment and purchase agreement programs for vital medical infrastructure developed by companies primarily manufacturing in the U.S. through the National Institutes of Health and [BARDA](#).
- Public Health Emergency Medical Countermeasures Enterprise (PHEMCE):
  - To require distributor input in the [PHEMCE](#), PAHPA should amend [42 U.S. Code § 300hh-10a - Public Health Emergency Medical Countermeasures](#) Enterprise paragraph (c)(2) to include "In carrying out subparagraph (C) of paragraph (1), the PHEMCE shall solicit and consider input from healthcare distributors."

### Clarifying the Role of Public and Private Partners

- To avoid confusion and multiple reporting channels, PAHPA must further clarify where the primary partnerships and coordination responsibility lie within the private sector supply chain. This clarification will ensure the timely delivery of medical products during an event.
- PAHPA should require a Government Accountability Office (GAO) report on the use of the Defense Production Act (DPA) to address the healthcare supply chain during catastrophic events, including the COVID-19 pandemic.

## Partnerships to Enhance Supply Chain Resilience

- Establish the Healthcare Distributor Advisory Group in PAHPA.
- PAHPA should require a GAO report on the existing healthcare supply chain data, and information flows from the private sector to the federal government.

## Preventing Disruptions to Ensure Supply to Essential Medicines

- The Department of Health and Human Services (HHS) and the Food and Drug Administration should work with manufacturers, distributors and other supply chain stakeholders to develop a drug shortage “early warning system” to detect a potential demand surge that may create a significant shortage or disruption.
- The Administration for Strategic Preparedness and Response ([ASPR](#)) and HHS should establish a list of 50 generic medications vital to public health during an event, including a Public Health Emergency (PHE). [H.R. 405](#) should also be included in PAHPA.

## Cybersecurity

- PAHPA should require a GAO report that outlines the full capabilities and limitations potential cybersecurity threats pose to the healthcare supply chain.
- PAHPA should include language to expand the use of the Public Health Emergency Fund (PHEF) funding to address cybersecurity. The expanded PHEF funding would be available to private healthcare supply chain stakeholders who suffer a cyberattack during an event that impacts public health.

## Future PHE Operations

- PAHPA should provide guidance on extensions of Emergency Use Authorizations after PHE ends, including timelines to work with the private sector on coordination. This would ensure supply chain continuity and availability of countermeasures after a PHE ends, which has proven crucial in catastrophic events such as COVID-19.
- PAHPA should address vaccine-tracking and distribution-reporting requirements by ensuring reporting system interoperability between the federal government and its U.S.-based healthcare distributors’ voluntary partners through annual testing and exercises.

## Conclusion

PAHPA is a unique opportunity to address the public and private sectors’ concerns to better prepare the nation for public health events while building a more resilient supply chain. HDA and its members recognize the importance of PAHPA, because distributors will use this critical piece of legislation to guide their ability to work with the federal government on all-hazards planning and response efforts.

Historically, Congress has enacted and reauthorized PAHPA in a bipartisan manner, and HDA and its members stand ready to assist and provide expertise for its reauthorization. The public and private sectors must work together to ensure the nation is ready to respond in steady-state and crisis times.

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### About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.