



Healthcare Distribution Alliance

HEALTH DELIVERED

July 10, 2023

The Honorable Bernard Sanders
The Honorable Bill Cassidy, M.D.
The Honorable Robert Casey
The Honorable Mitt Romney

Senate Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chair Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney,

We appreciate the opportunity to comment to the Senate Health, Education, Labor and Pensions (HELP) Committee on the discussion draft of the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization on behalf of the pharmaceutical distribution sector. The Healthcare Distribution Alliance (HDA) applauds the bipartisan efforts to reauthorize PAHPA in this Congress. The COVID-19 pandemic and recent local disasters have underscored the need for adequate preparedness and response to support public health needs in a crisis. The healthcare and public health sectors are bolstered by the authorities provided in PAHPA, so we appreciate your focus on this critical legislation.

HDA is the national trade association representing primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDA advocates on behalf of pharmaceutical wholesalers and distributors, leads the sector on relevant policy and fosters relationships across partner organizations. Healthcare distributors ensure the safe, efficient and reliable delivery of medications, vaccines and other critical medical products. HDA's members find the safest and most efficient ways to get products where patients need them continuously and reliably. Distributors provide necessary services to the healthcare supply chain; without distributors, manufacturers and pharmacies would face logistical challenges connecting approximately 1,400 manufacturers to more than 330,000 sites of care daily. HDA and its members recognize that PAHPA will shape healthcare preparedness and response policy for future events that may impact public health.

In March 2023, HDA [responded to the Senate HELP](#) request for information on PAHPA, in which we offered PAHPA recommendations. The recommendations provided focused on the potential for distributor capabilities to support [public health preparedness](#), such as increased [operational resilience](#), supply chain visibility, bidirectional data and information-sharing, and stockpiling strategies. Key recommendations previously submitted include:

- **Supply chain coordination:** HDA supports the primary objective of the [Supply Chain Control Tower \(SCCT\)](#), originally created to track the status of key products in the supply chain during the COVID-19 pandemic. HDA recommends that the SCCT be utilized at full operational capacity only during a public health emergency (PHE). Outside of a PHE, HDA recommends that the SCCT be maintained at a “warm posture” and be routinely tested to readily scale up for events.

Supply chain coordination to detect demand surge: HDA recommends exploring a public-private partnership (PPP) between the Food and Drug Administration (FDA) and the upstream private sector supply chain – manufacturers, distributors, and other relevant supply chain stakeholders on drug shortages. A PPP can be leveraged to develop a drug shortage “early warning system”, which may be used to detect a potential demand surge that could create a shortage or supply disruption.

- **Federal agency authorities:** HDA recommends that PAHPA builds on the work from the [PREVENT Pandemics Act](#) to clarify the roles and responsibilities of the Administration for Strategic Preparedness and Response (ASPR) and other federal partners to avoid multiple reporting channels for the private sector supply chain during an event.
- **Expansion of stockpiling capacity for medical countermeasures (MCM):** HDA recommends PAHPA build on the PREVENT Pandemics Act to improve preparedness and response planning for all-hazards, in partnership with the healthcare supply chain. Distributors have demonstrated the ability to support the federal government’s effort to expand medical countermeasure (MCM) deployment and stockpile capacity by leveraging supply chain partnerships. HDA recommends that this legislation outline the role of supply chain stakeholders in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), as well as a process to determine what Strategic National Stockpile (SNS) products can be managed using a Vendor Managed Inventory (VMI) strategy.

Section 2405 of the PREVENT Pandemics Act authorized the SNS to include manufacturers or distributors via a contract or cooperative agreement. Distributors are pleased to see that provision along with section 2406, which authorizes the Secretary to sell excess products from the SNS to other entities when the cost of maintaining these products in the SNS is not appropriate to meet the needs of the SNS and the transfer of these products does not compromise national security. To avoid sudden disruptions in the market due to the SNS releasing product, we urge for the SNS to work with distributors to put the product into the commercial market in a more stable manner. In addition to coordination between SNS and distributors on product release, we also want to ensure that VMI strategy is used to rotate SNS product which can be used in the commercial market (outside of events). To ensure that distributors help the SNS maintain readiness, HDA recommends the creation of a process within the PHEMCE to determine what products should be held by the SNS in VMI. HDA and its members

also recommend welcome testing these capabilities through annual tests and exercises between the public and private sector.

To build on existing partnerships from the COVID-19 pandemic response, healthcare distributors seek opportunities to improve coordination with the government to better respond to future events. This coordination will help in planning for future events, ensuring that both the private and public sectors have a common operating picture. HDA and its members recommend including language in PAHPA to establish a permanent Healthcare Distributor Supply Chain Advisory Group (HDAG) of industry and federal partners, managed by ASPR, to engage in regular communication and monitoring of the supply chain, flag potential disruptions, and collaborate on solutions. The HDAG should include ASPR, PHEMCE, healthcare distributors, and the Federal Emergency Management Agency (FEMA). The purpose of the HDAG is to examine possible methods to grow PPPs for future preparedness and response efforts. The federal government should also examine the coordination between the key agencies (i.e., FEMA, SNS) and the supply chain through annual testing and exercises, incorporating the HDAG in these activities.

This coordination also enables the private sector to ensure that there is planning on government procurement of product as well as the use of VMI to expand capacity. HDA urges Congress to consider incorporating parameters to ensure that excess product procured by the SNS is not dumped into the commercial market, creating an inventory challenge and disrupting the commercial market.

HDA and its members recommend that any contract between the SNS and distributors be at least five (5) years. There are considerable costs associated with standing up and maintaining warehousing for the SNS, which require stable contracts to ensure that investment in enhanced capability will be supported by that contractual relationship.

- **Vaccine tracking and reporting requirements:** PAHPA should address vaccine tracking and distribution reporting requirements by ensuring reporting system interoperability between the federal government and its U.S.-based healthcare distributor voluntary partners through annual testing and exercises.

Thank you for the opportunity to review the PAHPA discussion draft. HDA members are pleased that several recommendations provided have been incorporated into the draft, as we believe these recommendations are critical to public health readiness and national security.

- **Sec. 104. Pilot Program to Support State Medical Stockpiles**
 - HDA supports Sec. 104, which continues the pilot program that supports state medical stockpiles. HDA supports funding for state stockpiles, and we recognize that each state and region may face different public health threats due to geographic area. HDA believes distributors are essential partners for state

medical stockpiles because distributors can support these stockpiles with technical expertise, physical space, and strategies to rotate product to prevent expiration of stockpiled products.

- Public-private partnerships between state governments and distributors to support state stockpiles will enhance state medical stockpile readiness, and ensure that products are available for various hazards. Distributors have supported state level stockpile legislation (in New York and California, as examples) and continue to encourage states to develop state stockpiles with IT linkages and routine coordination with the SNS. As state stockpiles are created, HDA and its members strongly advise they are coordinated with the overall SNS strategies and can connect to the SNS IT linkages. This will ensure that the SNS has insight into what each state has stockpiled so they may supplement it in the case of an event. Further, we encourage these pilots to explore the use of the VMI strategy within their stockpiles.
- HDA supports the proposed GAO Report in Sec. 104. HDA and its members believe it is crucial to understand the impact of regional stockpiling approaches on the national public health readiness strategy. As regional stockpiling approaches are reviewed, HDA and its members encourage coordination and communication with private partners, like distributors, who help maintain the SNS and could help maintain state medical stockpiles.
- Sec. 201. All-Hazards Emergency Preparedness and Response
 - HDA supports Sec. 201, precisely page 19, lines 12-19.
 - HDA and its members support Sec. 201, which lays the groundwork for collaboration between HHS and relevant industry about supply chain vulnerabilities and supply capacity planning. During the COVID-19 pandemic, HDA's members provided the Department of Health and Human Services (HHS) with insights into the supply chain through the SCCT and see this as an area for further partnership to improve supply chain coordination.
- Sec. 202. Strategic National Stockpile and Material Threats.
 - HDA recommends that Sec. 202 includes H.R. 405, the [Essential Medicines Strategic Stockpile Act of 2023](#) (EMSSA) (118th Congress).
 - This legislation was introduced by Rep. Buddy Carter (R-Ga.) and Rep. Lisa Blunt Rochester (D-Del.) with the goal of amending the Public Health Service (PHS) Act to establish a pilot program that creates a six-month stockpile of fifty (50) generic drugs at risk of shortage, at the direction of the HHS secretary.
 - The bill language for H.R. 405 can be included as suggested:
 - *SEC. 202. STRATEGIC NATIONAL STOCKPILE AND MATERIAL THREATS.*
 - *Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—*
 - *(1) in subsection (a)—*
 - *(A) in paragraph (2)(B)(i), by striking subclause (IV) and inserting the following:*

- *Include the bill language for H.R. 405.*
 - *Change the rest of the section to carry the changes throughout the section and keep the existing language in Sec. 202.*
- HDA and its members recommend that Sec. 202 include language on the scope and operational status of the SCCT. Language on the SCCT should address the scope and operational status of the SCCT, incorporate parameters for when the SCCT would be fully operational (during a PHE), and provide requirements to ensure the protection of private sector data inputted into the SCCT.
 - Suggested language:
 - *The SCCT shall be fully operational during a public health emergency only. The SCCT may remain at a warm posture (with the ability to scale up for public health emergencies) between public health emergencies. The SCCT must consider antitrust regulations and laws regarding the industry data stakeholders submit to the SCCT. The SCCT must include protections to maintain security for industry data stakeholders submit to the SCCT.*
 - The inclusion of language on the SCCT can occur after the inclusion of H.R. 405.
- Sec. 204. Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)
 - HDA and its members support the inclusion of the distribution industry in activities and MCM planning conducted within the PHEMCE.
- Sec. 503. Vaccine Tracking and Distribution
 - HDA and its members support Sec. 503, specifically the funding authorization for influenza or pandemic vaccine distribution. During the COVID-19 pandemic and Mpox outbreak, HDA's members provided logistical support for vaccine and therapeutic distribution.

HDA and its members stand ready to provide our expertise to assist with the PAHPA drafting and reauthorization. If you have any questions or would like additional information, please contact Dr. Nicolette Louissaint by email at nlouissaint@hda.org.

Sincerely,



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