

March 29, 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 reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) on behalf of the pharmaceutical distribution sector. The Healthcare Distribution Alliance (HDA) applauds the bipartisan leadership to reauthorize PAHPA this year.

HDA represents primary pharmaceutical distributors, who serve as the vital connection between pharmaceutical manufacturers and dispensers. HDA's distributor members are the central link in the pharmaceutical supply chain, delivering critical and life-saving medicines and other medical supplies needed to support safe and effective healthcare delivery during both steady-state and crisis conditions. HDA takes that mission seriously, as exemplified by our members use of their capabilities during the COVID-19 pandemic to support vaccine and therapeutic distribution. HDA and its members recognize PAHPA will continue to shape healthcare preparedness and response policy and, as such, believe it is crucial for partnerships on supply chain coordination to continue.

In response to the PAHPA Request for Information (RFI) (March 15, 2023) to seek insights and perspectives to inform the PAHPA reauthorization, HDA and its members recommend the policy changes outlined below to ensure the nation's readiness for future events.

### **Program Effectiveness**

What specific changes could Congress make to improve the efficiency and effectiveness of current HHS programs and activities? Specifically:

#### *Public Health Emergency Coordination and Policy*

1. The responsibilities and authorities of the Secretary of Health and Human Services (HHS) prior to or during a public health emergency (PHE)

We believe that the responsibilities and authorities of the Secretary of Health and Human Services (HHS) are sufficient to respond to future threats. We would note, however, that the implementation of authorities by other parts of the Executive Branch, such as the Defense Production Act (DPA), would have to be coordinated with the HHS Secretary to ensure coordination and alignment with the public health response. We do not believe that the current authorities impede this coordination, but want to note that it is critical for there to be coordination of the use of authorities across the interagency during catastrophic events.

## 2. The authorities, duties, and functions of the Assistant Secretary for Preparedness and Response (ASPR)

**ASPR Clarification:** HDA recommends PAHPA builds on the work from the [PREVENT Pandemics Act \(PREVENT\)](#) to further clarify the scope and role of ASPR to guide preparedness and response to future events that impact public health security. PREVENT added authorities to ASPR in Section 2103 & Section 2104 to clarify roles and responsibilities for pandemic response. However, more can be done in PAHPA to ensure alignment between ASPR and the newly authorized White House office, as well as a clear partnership with specific parts of the private sector, to leverage the total capacity of the supply chain for all-hazards.

The current role and scope of ASPR include information sharing with stakeholders, managing public-private partnerships (PPPs), planning for medical surges, and situational awareness related to supply availability. HDA recommends using PAHPA to review how these roles align with other parts of the federal government and address differences in the federal agencies during events where the lead federal agency may need to change (i.e., cyber event, pandemic, natural hazard). Additionally, with the creation of the new Pandemic Preparedness and Response Policy Office within the White House (W.H.), new responsibilities will be assigned to this office, including serving as the principal advisor to the President for pandemic preparedness and response.

*Recommendation: PAHPA must further clarify where the primary partnerships and coordination responsibility with the private sector supply chain will lie to avoid confusion and multiple reporting channels to ensure the timely delivery of medical products during an event. Ensure that the new capabilities and coordination channels established during COVID-19 can be maintained through ongoing engagement and routine tabletop exercises.*

**Contractual Authorities:** ASPR should be given contracting and acquisition authorities like the Department of Defense (DOD). During the COVID-19 pandemic, ASPR stated it needed DOD support because it did not have flexible contracting acquisition authorities. ASPR is at a disadvantage to operate compared to the DoD because they do not have innovative procurement and acquisition authorities.

**Supply Chain Control Tower (SCCT):** During the COVID-19 pandemic, ASPR created the SCCT, to which distributors submitted data voluntarily. The SCCT was helpful for data illumination during the height of the COVID-19 pandemic. To continue the success of the SCCT, HDA recommends the PAHPA reauthorization includes language to create concrete parameters for the SCCT moving forward.

- **Parameters for when data-sharing occurs:** *The SCCT should be fully operational during a PHE only.* Healthcare distributors should have an established cadence of submitting data to the SCCT to avoid overburdening during a surge. *The SCCT should stay at a warm posture between events, which includes the ability to scale up for events.* HDA and its members believe the use of the SCCT can provide value during a public health emergency where supply chain coordination across industry and government can yield innovative solutions to avoid disruptions.

While we welcome the SCCT for coordination during PHEs, we believe that the control tower has a limited utility regarding routine disruptions or smaller-scale medical surge events. The creation of an 'early warning system' to anticipate and plan for supply chain disruptions or drug shortages is more appropriate than the SCCT remaining fully turned on during these scenarios.

- **Parameters for data protection:** *The SCCT should be mindful of antitrust considerations regarding the use of data submitted to it by private companies. The SCCT should also be required to maintain cybersecurity protections.* Private partners input raw data, including proprietary data, into the SCCT. There must be robust cybersecurity protections for submitted data to ensure data security within the federal government.
- **Parameters for data usage:** Data submitted to the SCCT should be used in ways that are cooperative and do not affect the commercial market. *HDA recommends the SCCT include private partners in annual testing and exercises.* The SCCT should be used regularly in tabletop exercises used to test response and preparedness for events.

Please reference the following report for more HDA perspectives on the SCCT and data illumination: <https://www.hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7dbfb048/HDA-Data-Illumination-Report.pdf>

**Supply Chain Disruptions and Drug Shortages:** The continuity of the supply chain is essential to avoid disruptions and potential drug shortages. Supply chain disruptions or drug shortages can impact the nation's public health response capabilities.

*Recommendation: HDA recommends that HHS and the FDA work with manufacturers, distributors and other supply chain stakeholders to develop a drug*

*shortages 'early warning system' to detect a potential demand surge that may create a significant drug shortage or product disruption.*

**Essential Medicines:** To prepare for potential drug shortages and disruptions, ASPR and HHS should establish a list of 50 generic medications vital to public health during an event that impacts public health, including a PHE. This can be accomplished by including [H.R. 405](#), the Essential Medicines Strategic Stockpile Act of 2023 (118th Congress), in PAHPA. Our nation has learned that we must take steps to further strengthen and secure the pharmaceutical supply chain for reliable patient access to medicines, no matter the conditions.

HDA supports the efforts to expand the public health industrial base. HDA welcomes the creation of the ASPR Industrial Base Expansion office as a helpful coordination point to review linkages in the supply chain and guide strategic investments regarding onshoring and nearshoring critical products to expand the medical industrial base. HDA and its members recognize the importance of diversifying the supply chain to ensure resilience and national security. This effort should focus on diversifying critical supply chains rather than diverting them. Additionally, distributor capabilities will remain able to ensure the delivery of products regardless of the country of origin.

*Recommendation: HDA recommends that ASPR and HHS establish a list of 50 generic medications vital to public health during an event, including a PHE. We also recommend the inclusion of H.R. 405 in PAHPA.*

For more HDA perspectives on essential medicines, please refer to the Supply Chain Resilience Assessment: High-Level Summary and Recommendations: <https://www.hda.org/getmedia/92505331-5f7d-401b-b099-3b05359ae280/Supply-Chain-Resilience-Assessment-High-Level-Summary-Recommendations.pdf>

## Medical Countermeasures Development and Deployment

### 1. The Strategic National Stockpile (SNS)

HDA members have been long-time partners of the SNS and support further strengthening the SNS through funding and additional authorities. The SNS manages the planning, stockpiling, and movement of medical countermeasures needed to protect Americans from various events that pose risks to public health, specifically products without a robust commercial market that must be maintained through the SNS to ensure availability. This requires a more vigorous threat planning process, including partnerships with distributors and other supply chain partners to determine how best to plan for products that might be in the commercial market but not at sufficient levels for a catastrophic event.

**Expanded vendor-managed inventory:** The PREVENT Pandemics Act (PREVENT) authorized but did not fund the SNS to support vendor managed

inventory (VMI) and warm base capacity. To support VMI, PREVENT authorized the SNS to include manufacturers or distributors via a contract or cooperative agreement. Distributors are pleased to see that provision in PREVENT. Still, distributors believe that going further to align this VMI strategy with continued investment and a robust threat analysis process will help enhance readiness.

We 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 6 - 8 weeks of a high-risk event. Certain medical countermeasures for events that impact public health are already circulating within the commercial market. Currently, the SNS does not have the capability to hold medical countermeasures to serve all Americans during an event that impacts public health. Distributor partnerships with the SNS expand the SNS response capabilities during events that impact public health.

*Recommendation: HDA recommends establishing a process to determine what products should be part of VMI. We also recommend establishing a process to determine how best to conduct ongoing threat assessment activities outside annual exercises and testing.*

*Recommendation: To support the SNS program and its partnerships, we recommend the SNS receives a funding authorization that, at a minimum, maintains the Fiscal Year 2023 appropriated funding level.*

**IT interoperability with the private sector:** The SNS should review its technology systems and be required to test them for interoperability with private sector inputs. There is an issue with the HHS/SNS systems connecting with private sector partners. The SNS should evaluate its technology systems annually through testing and exercises with the private sector. Ensuring connectivity of the HHS/SNS technology systems will ensure that private partners have the ability to implement changes to achieve and maintain interoperability with the HHS/SNS systems.

*Recommendation: HDA recommends including language in PAHPA to require the SNS to work with all U.S.-based healthcare distributors' voluntary partners on developing and maintaining Information Technology (IT) connectivity.*

**Prevent dumping of SNS supplies:** [Section 2406 of the PREVENT Pandemics Act](#) 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. Section 2406 can be further strengthened in PAHPA to include VMI solutions that allow a product to be commercially available before the SNS procures the product. HDA also recommends that if a product is procured and there is an excess of that product in the SNS, PAHPA provides parameters to establish the coordination of transferring that product to the commercial market. Amending Section 2406 in PAHPA will establish 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.

*Recommendation: HDA recommends that the SNS reviews its management and reimbursement practices for medical products with distributors before procuring certain supplies and in cases where there is a product excess.*

To see more HDA perspectives on the SNS, please refer to the Supply Chain Resilience Assessment: High-Level Summary and Recommendations:  
<https://www.hda.org/getmedia/92505331-5f7d-401b-b099-3b05359ae280/Supply-Chain-Resilience-Assessment-High-Level-Summary-Recommendations.pdf>

## 2. The Biomedical Advanced Research and Development Authority (BARDA)

**BARDA:** HDA and its members believe that PPPs can be strengthened through BARDA. Distributor partnerships with domestic medical countermeasures (MCM) manufacturers will incorporate more joint planning and improve supply chain resilience. Joint planning between a manufacturer and a distributor will provide better access to the commercial market and allow the supply chain to plan for MCM response more effectively. Stronger PPPs lead to less drastic healthcare supply chain disruptions and bolster response to events that impact public health.

*Recommendation: We recommend the federal government maintains and expands loan, grant, direct investment, and purchase agreement programs for vital medical infrastructure developed by companies primarily manufacturing in the United States through BARDA.*

## 3. Project BioShield

**Include distributors:** Project BioShield can be strengthened if distributors are utilized as partners to hold and, when appropriate, distribute medical countermeasures. Expanding the focus of Project BioShield to include distribution will ensure the availability of developed medical countermeasures during an event that impacts public health.

*Recommendation: HDA supports Project BioShield and recommends that it is required to include distributor partnerships to hold and manage developed medical countermeasures.*

## 4. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related strategy, implementation plan, and budget plan

**Inclusion of healthcare distributors in PHEMCE:** HDA would like PHEMCE to solicit distributor input on strategy development for medical countermeasures deployment, distribution, and dispensing. HDA views the inclusion of distributors in

preparedness and response planning as an opportunity for distributors to utilize their expertise in preparations for responding to an event that impacts public health.

*Recommendation: To require distributor input in PHEMCE, HDA recommends amending 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."*

## 5. Emergency Use Authorizations and related authorities

**EUA Extension Guidance:** PAHPA should consider providing guidance on extending EUAs beyond a PHE. A plan for the extension of EUAs of medical countermeasures ensures product distribution after a declared PHE ends. For example, the EUA extension that covers COVID-19 vaccinations and therapeutics can continue after the current PHE ends. HDA recognizes that the Food and Drug Administration (FDA) can extend EUAs beyond a PHE and welcome this happening in advance to ensure appropriate planning across the supply chain.

*Recommendation: HDA recommends PAHPA provide guidance on EUA extensions after a PHE ends, including timelines to work with the private sector on coordination. This ensures supply chain continuity and availability of countermeasures after a PHE ends, which has proven important in catastrophic events such as COVID-19.*

## Support for Jurisdictional Preparedness and Response Capacity

### Vaccine tracking and distribution

During the COVID-19 pandemic, healthcare distributors used their expertise, infrastructure, and existing capabilities to distribute COVID-19 vaccines. Each type of COVID-19 vaccine had different storage requirements for safe and effective distribution. To ensure proper tracking and distribution, plans for different medical countermeasures are tested bi-annually, including connectivity to the government reporting systems.

*Recommendation: HDA recommends PAHPA addresses 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.*

### Policies for the inclusion of at-risk individuals in public health emergency preparedness and response activities

HDA recommends, when appropriate, policies to address the administration of medical countermeasures to at-risk individuals including distribution plans to address the needs of individuals who are at-risk or live in medical deserts. We also

recommend distribution strategies include Federally Qualified Healthcare Centers (FQHC), community pharmacies, and ancillary sites of care that serve at-risk individuals.

Based on distributor experiences, 'at-risk' populations can include different individuals depending on the circumstance, and impacts the facilities prioritized during a public health emergency. It would be helpful involve distributors in plans to be designed to address the specific needs of the at-risk population(s). We recommend that government response plans are designed to include distributors in a manner that can leverage their nimbleness, allowing for flexibility to adjust to the needs of at-risk populations.

### **Gaps in Current Activities & Capabilities**

1. What gaps do you see in the PAHPA framework, or how it has been implemented to date? (These gaps could be related to any of the programs noted above or other aspects of the public health and medical preparedness and response ecosystem that are otherwise currently unaddressed.)

HDA and its members believe there are gaps within the SNS framework. The SNS works with commercial partners, primarily healthcare distributors, to maintain and deploy medical countermeasures. There is a gap in the ability of the HHS/SNS technology systems to connect to private partners. An interoperable SNS/HHS technology system will boost the SNS's efficiency. There is also a need for more communication between the SNS and distributors on procuring and cycling out the product through VMI. A plan to use VMI and create a permanent Healthcare Distributor Supply Chain Advisory Group to engage in regular supply chain communication and monitoring will establish guardrails to protect both the SNS and the commercial market.

2. Additionally, aside from currently authorized programs and activities, what gaps exist in HHS' capabilities, and what types of activities or authorities are necessary for HHS to fulfill the intent of PAHPA and related laws?

**Healthcare Distributor Supply Chain Advisory Group:** During the COVID-19 pandemic response, healthcare distributors were essential partners to the federal government. Healthcare distributors seek opportunities to improve partnerships to better respond to future events.

We 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, Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), healthcare distributors, and Federal Emergency Management



Agency (FEMA). The purpose of the HDAG is to examine possible methods to grow PPPs for future preparedness and response efforts.

*Recommendation: HDA and its members request the creation of the HDAG in PAHPA.*

**GAO Report on Data Sources:** HDA recommends requiring a Government Accountability Office (GAO) report on the existing healthcare supply chain data and information flows from the private sector to the federal government. This GAO report will provide both the public and private sectors with a clearer picture of existing tools that can be better leveraged by ASPR 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 PHEs. A deeper understanding of the data and information flows will allow both the public and private sectors to better prepare and respond to events that impact public health.

*Recommendation: HDA recommends PAHPA requires a GAO report on the existing healthcare supply chain data and information flows from the private sector to the federal government.*

**GAO report on the use of the Defense Production Act (DPA):** During the COVID-19 pandemic, the DPA was used to secure components needed and expand medical countermeasures. Public and private stakeholders benefit from a better understanding of the DPA and its future uses.

*Recommendation: To understand the past and future uses of the DPA, HDA recommends a GAO report on the use of the DPA to address the healthcare supply chain during catastrophic events, including the COVID-19 pandemic.*

## **Partnerships**

What specific steps could Congress take to improve partnerships with states and localities, community-based organizations, and private sector and non-government stakeholders, such as hospitals and health care providers, on preparedness and response activities? For example:

1. How can these entities be better supported in appropriately engaging with the federal government to understand available resources, capabilities, and expectations prior to, during, and following a public health emergency?

Public-private partnerships (PPPs) between the federal government and private healthcare supply chain stakeholders are critical to responding to events that impact public health. Distributors have held partnerships with FEMA, the White House, and HHS to share information on supply chain capabilities, coordination with the SCCT to provide information on product availability for key items and closed distribution system for COVID-19 vaccines and therapeutics.

The federal government can better support private partners to understand the available resources, capabilities, and expectations prior to, during, and following a public health emergency using contracts or cooperative agreements. *To better support PPPs, HDA recommends the following:*

- *Invest resources in establishing PPPs during steady-state and crisis conditions.*
- *Leverage prior collaboration between public sector entities and private industry to build on existing relationships and infrastructure from previous PPPs.*
- *Partner with the private sector to utilize expertise, existing infrastructure, networks, relationships, manufacturing abilities and technologies whenever possible.*
- *Solicit private sector input in the development of data-sharing efforts to bolster supply chain resilience.*
- *Require partnership duration of five years.*

HDA believes an effective PPP should include jointly agreed upon and mutually beneficial goals, collaborative and consensus-based decision-making, trust-based relationships, cooperative interactions among partners, and shared accountability for outcomes and results.

HDA and its members stand ready to provide our expertise to assist with the PAHPA reauthorization. Distributors will use PAHPA to guide their ability to work with the federal government on all-hazards planning and response efforts. If you have any questions or would like additional information, please contact Dr. Nicolette Louissaint by email at [nlouissaint@hda.org](mailto:nlouissaint@hda.org).

Sincerely,



Dr. Nicolette Louissaint  
Senior Vice President, Policy and Strategy Planning