



Healthcare Distribution Alliance

PATIENTS MOVE US.

June 25, 2020

The Honorable Lamar Alexander
Chairman, Senate Health, Education, Labor and Pensions Committee
U.S. Senate
428 Senate Dirksen Building
Washington, DC 20510

Dear Chairman Alexander:

On behalf of the Healthcare Distribution Alliance (HDA), I offer this letter in response to your request for information on your white paper “Preparing for the Next Pandemic.” The nation’s primary pharmaceutical distributors have been and will continue to be committed to assisting the country and our frontline healthcare providers during the COVID-19 pandemic, as well as all public health emergencies, and we appreciate the opportunity to provide feedback to your recommendations.

Over 92 percent of medications shipped in the United States arrive at their dispensing location because of an HDA member company. The organization’s 35 distributor members are working around-the-clock to enhance our national supply of critical medications and supplies required to fight this pandemic, protect our frontline providers and enable treatment for patients. Our members have historically been partners to the federal government in the warehousing and delivery of medical supplies from the Strategic National Stockpile (SNS) and have been supporting national, state, local entities and healthcare providers during this crisis.

As the pharmaceutical supply chain responds to public health emergencies, healthcare distributors proactively leverage prior emergency response experience and expertise to support the entire supply chain and help wherever we can. HDA members are in the business of finding the safest and most efficient ways to get products to patients where needed, working as the vital link between the nation’s 1,300 pharmaceutical manufacturers and more than 180,000 healthcare delivery settings. This is our strong suit, and we continue to serve as a strategic partner and resource to the federal and state agencies running the response efforts.

Below please find our feedback on the recommendations outlined in your white paper, as well as responses to a number of the proposed questions. We kept our responses to those questions that were related to the pharmaceutical distribution industry.

Feedback on Recommendations

RECOMMENDATION 3.1: Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.

We encourage the federal government to utilize the capabilities of the nation's existing pharmaceutical distribution infrastructure, including HDA's 35 member companies. Distributors expedite and streamline efforts during public health emergencies, and in the continuing COVID-19 response, particularly as treatments and vaccines emerge. Wholesale distributors have existing warehouse facilities across the United States, established relationships with manufacturers and healthcare providers, sophisticated ordering systems and efficient shipping networks to swiftly reach every part of the United States. We believe that attempting to build out separate distribution channels would be redundant, inefficient and costly.

HDA also supports significant attention to development of any resources and/or incentives manufacturers may need to ramp up production of products to meet both customary domestic supply needs and during a pandemic or other health emergency.

RECOMMENDATION 3.2: States should establish distribution plans and procedures to better inform and communicate with health care providers that request supplies. The Strategic National Stockpile should provide states, territories, and tribes with guidance on best practices to coordinate and distribute medical supplies, including procedures to request resources from the federal stockpile.

Strengthening communication between federal and state agencies and the pharmaceutical supply chain is imperative to maintaining and leveraging existing distribution channels, and appropriately managing distribution of medical products during a declared state of emergency. Established plans and increased communication related to the SNS will help prepare the supply chain to efficiently respond and coordinate.

RECOMMENDATION 3.3: Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.

Pharmaceutical wholesale distributors are very experienced in managing product expiry for all medicines, including those essential medicines and medical countermeasures used to treat coronavirus patients. We anticipate that wholesale distributors would employ a model where they increase inventories of specific products from the current practice of about 28 days of product on hand to a full six months of product (a practice companies

already occasionally employ for select products). They would continue to fulfill regular customer orders from this expanded inventory while continually replenishing the depleted inventory with new product ordered from manufacturers to maintain the six-month supply. This replenishment strategy would allow distributors to manage product dating and avoid expiry. In the event the SNS is activated to respond to a pandemic or other health emergency, the expanded inventory would provide distributors with additional inventory capacity to swiftly meet increased patient and customer demand. Please note that for this to work, the expanded inventory dedicated to SNS would need to be identical to desired products purchased by each distributor's customers.

RECOMMENDATION 3.4: The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.

During a pandemic, as new treatments and vaccines become available, HDA supports the recommendation that the federal government partner with and provide detailed guidance, in advance, to pharmaceutical distributors on how essential treatments and vaccines should be distributed. It is critical that federal and state authorities work together to designate priority populations, localities and eligible facilities, and communicate that information to the supply chain to ensure that as products are approved and manufactured, decisions and plans for distribution can be made.

HDA distributor members stand ready to maximize the efficiencies of the existing private-sector distribution system to support response efforts to deliver treatments and vaccines to where they are most needed. This is particularly important when a new treatment or vaccine, related to the pandemic, is first entering the marketplace. Distributors have significant experience in delivering new medicines expeditiously and can be integral to ensuring:

- Inventories are pre-positioned in the supply chain to help facilitate ready access to providers;
- Drugs are available to providers as swiftly as possible;
- Treatments and vaccines can reach facilities designated under each state's emergency preparedness plan; and,
- Distribution plans comply with existing federal and state regulations.

RECOMMENDATION 3.5: Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.

We recommend that the federal government work closely with state and local authorities and public health agencies both to improve understanding of the demand for medical supplies and to provide better visibility into the SNS system. We believe a productive, collaborative relationship with state and local partners would build trust in the SNS response criteria and capabilities, permit more efficient allocations when demand is urgent

and resources are scarce, avoid redundant efforts, prevent hoarding and lower overall costs.

RECOMMENDATION 3.6: Better leverage the support provided by FEMA and their emergency management experience and assets by improving a coordinated process between HHS and FEMA to more rapidly distribute supplies to states, health care providers, and other entities on the front lines, while utilizing HHS expertise with respect to public health and medical care and medical supplies.

To facilitate uninterrupted access to the pharmaceutical and healthcare products HDA members provide, we encourage seamless communication (from federal and state agencies) and interagency collaboration to identify and minimize inefficiencies and gaps in preparedness and response as well as provide guidance to the industry.

Further, coordination between the public and private sector is essential to effectively addressing challenges stemming from any declared state of emergency. During the COVID-19 pandemic response, pharmaceutical distributors have been in daily communication with Federal Emergency Management Agency (FEMA), Food and Drug Administration (FDA), Drug Enforcement Administration (DEA) and other federal agencies as well as state governments to respond to the unique challenges and remove any regulatory barriers that can slow down or impede access to medicines needed by healthcare providers.

RECOMMENDATION 5.1: Congress must clarify who is in charge and has the ability and authority to keep a continued focus on preparedness for pandemics and other major public health threats when other priorities may seem more pressing, and improve how federal agencies will coordinate during a pandemic. These roles and responsibilities must also be clearly communicated to states and local governments so they can include this information in their own preparedness planning.

During times of declared public health emergencies, HDA supports a consolidated point of contact within the federal government to serve as a conduit to provide guidance to and interact with the healthcare supply chain. This coordination will help leverage existing supply chain resources and expertise.

Responses to select questions that are distributor-specific

Tests, Treatments and Vaccines

4. How can the federal, state, and private sector work together to more effectively distribute and administer treatments and vaccines?

We encourage the federal and state governments to utilize the capabilities of the nation's existing pharmaceutical distribution infrastructure to expedite and streamline efforts during times of public health emergencies and in the continuing COVID-19 response, particularly as treatments and vaccines emerge. Wholesale distributors have existing warehouse facilities across the United States, established relationships with manufacturers and healthcare providers, sophisticated ordering systems, and efficient shipping networks to swiftly reach their customers. We believe

that attempting to build out separate distribution channels would be redundant, inefficient and costly.

HDA distributor members stand ready to maximize the efficiencies of the existing private-sector distribution system to support response efforts to deliver treatments and vaccines to where they are most needed. This is particularly important when a new treatment or vaccine, related to the pandemic, is first entering the marketplace. Distributors have significant experience in delivering new medicines expeditiously and can be integral to ensuring:

- Inventories are pre-positioned in the supply chain to help facilitate ready access to providers;
- Drugs are available to providers as swiftly as possible;
- Treatments and vaccines can reach facilities designated under each state's emergency preparedness plan; and,
- Distribution plans comply with existing federal and state regulations.

8. How can the United States better leverage public-private partnerships, industry, and academic institutions?

To facilitate uninterrupted access to the pharmaceutical and healthcare products HDA members provide, we encourage seamless communication (from federal and state agencies) and interagency collaboration to identify and minimize inefficiencies and gaps in preparedness and response as well as provide guidance to the industry.

Coordination between the public and private sector is essential to effectively addressing challenges stemming from any declared state of emergency. During the COVID-19 pandemic response, pharmaceutical distributors are in daily communication with FEMA, FDA, DEA and other federal agencies as well as state governments to respond to the unique challenges and remove any regulatory barriers that can slow down or impede access to medicines needed by healthcare providers.

10. Are additional or more predictable liability protections needed to incentivize manufacturers of medical products that are not approved or cleared by the FDA for use during a certain emergency to scale up manufacturing capacity?

HDA recommends that any liability protections considered for manufacturers also be extended to pharmaceutical distributors, as they have been in the past, most recently in the Families First Coronavirus Response Act (PL 116-127). Further, we support liability protections for businesses designated as essential critical infrastructure by the Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency's (CISA) guidance, provided worker protections are maintained.

Stockpiles, Distribution, and Surges – Rebuild and Maintain State and Federal Stockpiles and Improve Medical Supply Surge Capacity and Distribution

1. How can the Strategic National Stockpile be better managed and how can Congress increase oversight and accountability?

HDA encourages the federal government to utilize the capabilities of the nation's existing pharmaceutical distribution infrastructure to expedite and streamline efforts during times of public health emergencies. HDA recommends the following to improve the operation of the SNS:

- Development of any resources and/or incentives manufacturers may need to ramp up production of products to meet both customary domestic supply needs and manufacture additional inventories that exceed typical customer demand to be used during a pandemic or other health emergency.
- Dedicated, long-term funding to acquire additional inventory commensurate with increases in capital and carrying costs, inventory management and replenishment fees.
- Increased communication from the SNS to provide additional data about product availability. We recommend that the federal government work closely with state and local authorities and public health agencies both to improve understanding of the demand for medical supplies and to provide better visibility into the SNS system. We believe a productive, collaborative relationship with state and local partners would build trust in the SNS response criteria and capabilities, permit more efficient allocations when demand is urgent and resources are scarce, avoid redundant efforts and lower overall costs.

2. How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?

Recognizing the costs of carrying excess inventory, we do not believe acquisition and storage of additional product would be efficient or prudent for all but the largest hospital systems. We strongly encourage the federal and state governments to work with wholesale distributors that have the existing infrastructure, healthcare provider customer relationships, expertise and proven capabilities to provide management and logistics support to their customers, including hospital systems.

3. What steps should be taken to ensure that health care providers and first responders have the supplies they need, such as personal protective equipment?

Distributors are in the business of finding the safest and most efficient ways to get products to patients where needed, working as the vital link between the nation's 1,300 pharmaceutical manufacturers and more than 180,000 healthcare delivery settings. This is their strong suit and they serve as a strategic partner and resource to their healthcare provider customers.

4. As states and hospitals establish or build their own stockpiles, how will they know what supplies to stockpile? What guidance should the federal government provide on what medical supplies are appropriate? and,

5. Could states and hospital systems establish their own vendor managed inventory programs with manufacturers and distributors? Should the federal government or states contribute to such hospital stockpiles?

Pharmaceutical distributors are committed to working closely with the federal government to provide visibility of inventories of essential medicines and medical countermeasures maintained in the SNS and to work closely with state and federal authorities to distribute SNS products where they are needed most. Apart from this visibility into pharmaceutical supply chain, we

believe it is equally critical to have visibility into real patient demand data. Better metrics around the demand for medical products would aid in matching inventory and customer orders to better manage allocation and curtail hoarding.

We recommend that the federal government work closely with state and local authorities and public health agencies both to improve understanding of the demand for medical supplies and to provide better visibility into the SNS system. We believe a productive, collaborative relationship with state and local partners would build trust in the SNS response criteria and capabilities, permit more efficient allocations when demand is urgent and resources are scarce, avoid redundant efforts and lower overall costs.

Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency

During times of declared public health emergencies, HDA supports a consolidated point of contact within the federal government to serve as a conduit to provide guidance to and interact with the healthcare supply chain. This coordination will help leverage existing supply chain resources and expertise.

As it relates to a public health emergency like the COVID-19 pandemic, as HHS oversees the FDA, CDC and the SNS, we believe that HHS is the logical department to coordinate the whole of government response. We encourage continued collaboration with their colleagues at DHS (including FEMA and CISA), Department of Defense, Department of Labor (including Occupational Safety and Health Administration) and Department of Justice (including DEA) as well as state governments to coordinate response efforts.

We also support the concept of a Supply Chain Control Tower model as set forth in the Request for Information for restructuring the Strategic National Stockpile.

Coordination among federal agencies and between the public and private sector is essential to effectively addressing challenges stemming from any declared state of emergency. During the COVID-19 pandemic response, pharmaceutical distributors are in daily communication with FEMA, FDA, DEA and other federal agencies as well as state governments to respond to the unique challenges and remove any regulatory barriers that can slow down or impede access to medicines needed by healthcare providers.

To further facilitate uninterrupted access to the pharmaceutical and healthcare products HDA members provide, we encourage seamless communication (from federal and state agencies) and interagency collaboration to identify and minimize inefficiencies and gaps in preparedness and response as well as provide guidance to the industry.

Conclusion

Every day, HDA distributor members are committed to doing what is necessary to ensure hospitals, healthcare providers, pharmacies and other sites of care have access to the medicines and healthcare products that patients need. This public health crisis is no different. Distributors

are rising to the challenge, supporting our supply chain partners, and doing everything possible to ensure continuous operations in the healthcare system during this unprecedented time.

We look forward to continuing our work with the administration, Congress and federal and state authorities to respond to the current COVID-19 pandemic and preparing for future pandemics and public health emergencies. Please let us know if we can answer any questions or provide additional information.

Sincerely,

A handwritten signature in black ink that reads "Chester W. Davis, Jr." in a cursive script.

Chester "Chip" Davis, Jr.
President and Chief Executive Officer (CEO)
Healthcare Distribution Alliance (HDA)