Safeguarding Patient & Provider Access to Critical Medical Supplies

As the United States continues to address the spread of the coronavirus, strengthening the healthcare supply chain is more important than ever before. The Healthcare Supply Chain Association (HSCA) – which represents the sourcing and purchasing partners to virtually all of America's hospitals and the vast majority of long-term care facilities, surgery centers, clinics, and other healthcare providers – suggests the following administrative and policy solutions to safeguard patient and provider access to critical medical supplies.

Short Term Policy Solutions That Should Be Immediately Pursued to Help Address the COVID-19 Pandemic

Proposal:	Policy Details:
Support Federal, State, & Regional Stockpiling Efforts & Increase Public-Private Collaboration to Fill Supply Gaps	• Public and private stakeholders should continue to coordinate and engage in appropriate information-sharing to help support response efforts, leverage expertise, and enable a comprehensive response to public health crises. • The Strategic National Stockpile (SNS) plays a critical role in our nation's preparedness and response efforts, serving as a stopgap. Policymakers should ensure SNS has access to the resources and funding it needs to support its response capabilities. Further, there should be increased private sector visibility into SNS content and allocation efforts to support capacity and avoid redundancies. GPOs as supply chain leaders have helped to bridge supply gaps during the pandemic, and this increased visibility will greatly aid efforts to meet the timely critical needs of U.S. healthcare providers to fight COVID-19 and future pandemics. • SNS should also maintain, at a minimum, a 90-day supply of critical medical supplies and make key stockpile products available to the private sector prior to expiration, rotating in new products in order for efficient distribution as appropriate. • Authorities should leverage the expertise of SNS for technical assistance and guidance for state and regional stockpiles and consider matching grants to assist with setup and/or maintenance.
Enhance Visibility into the Source & Location of Finished Products & Raw Materials	• Enable the U.S. Food and Drug Administration (FDA) and other key federal partners such as the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS), Department of Defense (DOD), and Drug Enforcement Administration (DEA) to have greater visibility into the source and location of manufacturing of medical products and permit access to that information along with related reporting of anticipated disruptions or discontinuations on a national and regional level in advance of a public health emergency. • Solutions should include enhanced reporting measures such as information regarding the volume of active pharmaceutical ingredients (API) and other raw materials along with expected

	duration of disruption. Reports and updates should be issued on a semi-annual basis.
Advance Domestic Manufacturer Incentives for Finished Products & Raw Materials	• Policymakers should explore domestic manufacturer incentives such as public-private partnerships, regulatory flexibility, long-term contracts, 0% interest loans, infrastructure investment, tax credits for domestic manufacturers operating in certain Opportunity Zones, and incentives for advanced manufacturing. • Increasing domestic manufacturing as part of a resilient, geographically diverse global supply chain is a long-term process and should be a public health and national security priority. Policy solutions should include long-term domestic manufacturing incentives to ensure a sustainable approach.
Leverage Regulatory Flexibility to Safeguard Product Continuity Amid COVID-19 Response Efforts	• FDA should work to ensure Emergency Use Authorizations (EUAs) of critical medical products are extended, building upon FDA's significant efforts to-date to ensure timely needed access to medical supplies. • Policymakers should advance policy solutions that support administrative efficiencies and streamline response efforts.
Safeguard the Supply Chain from Counterfeit Products	• Policymakers should pursue solutions like the Safeguarding Therapeutics Act (H.R. 5663), which enhances FDA's authority to destroy counterfeit drugs and medical devices at American ports of entry, preventing such products from entering the supply chain and helping to ensure a safe and reliable supply of products.
Continue to Provide Tariff Relief for Critical Medical Products During the COVID-19 Pandemic	• As the United States works to address the COVID-19 pandemic, continued exclusion of critical medical products during this time of unprecedented demand is an important step to ensure continued patient and provider access to products essential to the fight against COVID-19.

Long Term Policy Solutions That Should Be Pursued to Help Ensure the Supply Chain is Prepared for Future Disruptions

Proposal:	Policy Details:
Expand FDA Drug and Device Shortage Lists & Update Its List of Key 503B Compound Drugs	• FDA should expand its list of drug shortages to include drugs that are experiencing significant national – as well as regional shortages – based on strength, dosage (e.g., pediatrics), and formulation. • FDA should also be provided access to critical data regarding inventory levels for essential medications and their API and key starting materials to help gauge capacity levels and support manufacturing efforts to ramp up production when needed. • FDA should update, on a semi-annual basis, its list of drugs that may be compounded by 503B outsourcing facilities. • FDA should consider expedited reviews of certain supplemental applications for drugs in shortage. FDA should also consider expedited review for drugs and devices that require premarket approval in case of an anticipated shortage, and policymakers should provide FDA with the authority to request information on medical device component parts and raw materials to support the security of the U.S. medical supply chain.
Advance Generic Drug Competition to Reduce Drug Prices	• Policymakers should advance policy solutions that increase competition in the generic drug marketplace such as incentives for advanced manufacturing. • Other solutions include eliminating pay-for-delay and other tactics (e.g., those addressed in the Fairness in Orphan Drug Exclusivity Act or H.R. 4712) that some brand name manufacturers use to prevent or delay generic competitors from entering the marketplace and hinder patient access to affordable medicines. • Policy measures should support and sufficiently resource FDA overseas inspection efforts. This will aid visibility into product information that is integral to stakeholders' ability to assess quality. • Policy solutions that support access to critical medicines such as the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act (H.R. 4866), which considers how emerging technologies, such as advanced manufacturing technologies like continuous pharmaceutical manufacturing, may increase timely quality production of needed medicines.
Adjust Aggregate Production Quotas to Mitigate Injectable Narcotic Shortages	• While the Drug Enforcement Administration (DEA) acted quickly to temporarily increase aggregate production quotas to aid acute patient care amidst the pandemic, DEA should develop a nimble and responsive process to increase quotas more broadly for injectable narcotics as part of institutional care to help prevent and address shortages.

	• Specifically, DEA should differentiate quotas by dosage and form in order to better meet provider needs for injectable narcotics- which are distinct from oral opioids and critical to in-patient medical care- while continuing to address the opioid epidemic.
Promote Critical Access to, in Adoption of, Biosimilar Medications	• Policymakers should consider solutions that support timely access and uptake of biosimilars, including addressing tactics that some brand name manufacturers use to prevent or delay biosimilar competitors from entering the marketplace such as patent abuse. • FDA should also streamline regulatory requirements for biosimilars, including eliminating comparative effectiveness studies when scientifically appropriate. • CMS should further examine payer policies that may prevent the adoption and usage of biosimilars and should work with other relevant organizations to consider how payer policies can better incentivize the adoption of biosimilar products.
Promote Data Standardization and Integration Throughout the Supply Chain	• In order to improve accurate reporting and patient safety, unique device identifiers (UDIs) should be included in product recall and safety notices to enable healthcare providers to quickly identify and withdraw relevant products. • Increasing accuracy and quality of supply chain data will help enhance supply chain resiliency and promote traceability. Data should include information regarding the location of active pharmaceutical ingredients (APIs) of raw materials and therapeutics.
Increase Provider Access to Critical Medical Products Through Technological Advancements	• Policymakers should continue to support the development and exploration of innovative technologies and programs that ease demand and can spur access to key medical products, such as SNS' efforts to explore reusable PPE technologies through its research program. • Authorities should also issue clear guidance to assist the healthcare industry on the use of ethylene oxide (EtO) for sterilization of medical supplies. They should also actively assess risks of specific medical product shortages and related capacity levels to inform efforts and availability for medical care.