

**AdvaMed Response to the Department of Health and Human Services, Office of the  
Assistant Secretary for Preparedness and Response (HHS/ASPR)  
Request for Information on the Strategic National Stockpile**

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To: [SNSsolicitationseye@cdc.gov](mailto:SNSsolicitationseye@cdc.gov)

RFI: 75A50120NEXTGENSNS

### **Introduction**

The Advanced Medical Technology Association (AdvaMed) would like to thank the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) for soliciting feedback on the Strategic National Stockpile (SNS). Recognizing that the COVID-19 pandemic has tested the SNS unlike any other time in history and calls for a full reassessment of its structure, capabilities and role during a pandemic – the current one and beyond - AdvaMed respectfully submits the following comments.

### **About AdvaMed**

Headquartered in Washington, D.C., AdvaMed is the world's largest medical technology trade association, with over 400 member companies ranging from the largest multinationals to the smallest innovators and companies. AdvaMed members manufacture the full range of technologies deployed in the COVID-19 fight including ventilators and oxygen therapies, personal protective equipment like masks and gowns, and diagnostic tests that detect the infection, guide treatment, and determine if individuals exposed have potentially developed immunity to the virus. In addition, our member companies' technologies extend beyond these three core areas. They also manufacture the hospital beds, dialysis machines and other critical medical supplies necessary to care for COVID-19 patients. Finally, as vaccines and therapies come on the horizon, our members that manufacture pharmaceutical reagents, lab equipment and injection delivery devices will be critical in this massive effort.

### **General Comments**

The COVID-19 crisis has demonstrated that the medical technology industry can respond quickly and effectively to meet the needs of patients and health care providers. Almost overnight, AdvaMed's member companies refocused their operations – expanding production and capacity to develop and manufacture the medical technologies that are critical to our country's fight against the pandemic, and arming health care workers on the frontlines with the tools they need to save lives.

To continue the fight against COVID-19 and to prepare for future extraordinary health care-related crises requires a concerted and collaborative effort, with government and industry working together, AdvaMed has identified and developed a white paper (available upon request) around the following key principles.

- ✓ **Storing sufficient supplies** in the strategic national stockpile to meet any initial surge in demand from any future health care crisis;

- ✓ **Keeping supply chains open** so that medical technology companies can efficiently access the components and raw materials they need to ramp up production;
- ✓ **Allocating in advance**, through careful planning, where and how to get crucial medical supplies to those most in need; and
- ✓ **Investing in America** to support a strong domestic medical technology industry that will continue to meet the needs of U.S. patients and health care providers.

### **Strategic National Stockpile Vision:**

AdvaMed supports the HHS/ASPR's stated objectives of *more coverage, more insights, more capability and less vulnerability*. The SNS has a critical role in filling gaps during surges in demand where the state and local authorities' stockpiles are overwhelmed. The COVID-19 pandemic presents a unique and historic challenge in terms of the role of the SNS given the prolonged nature of the pandemic and uncertainty of bringing the virus under control as the US reopens. The extraordinary ramping up undertaken by the medical devices industry has proven effective and adequate to ensure Americans have the medical supplies and technologies they need to care for COVID-19 patients and support frontline and healthcare workers.

Given this progress, as the government undertakes this initiative to overhaul the SNS and its response capabilities, it should be mindful not to hinder or disrupt existing supply chains and industry efforts to continue to ramp up production and accelerate delivery of critical medical supplies during the pandemic. Experts have noted that the SNS essentially serves as a large distributor during "large scale" events for a "limited period of time." Given that COVID-19 has created an extended public health event, it's critical to consider how the SNS will function and operate alongside the private sector throughout this crisis and expand the SNS functionality to reflect long term crises. This dynamic highlights the need to have a robust public private sector collaboration throughout the pandemic and Federal Emergency Management Agency's (FEMA) Voluntary Agreement is one example of a framework that could support these kinds of consultations.

In this vein, AdvaMed welcomes the government's emphasis on public-private partnerships as a critical element of the SNS structure and functioning. Given the complexities of doing a top to bottom reassessment of the SNS, and working to develop the capabilities, coverage and visibility envisioned in the new structure, AdvaMed would like to recommend that HHS/ASPR hold a series of public meetings or townhalls to explain the government's vision in more detail including its expectations for the role of the private sector. This kind of engagement could include an opportunity for medical technology and supply manufacturers to make proposals to HHS/ASPR on their technologies which might be eligible for the SNS.

Following that exercise, AdvaMed recommends that HHS/ASPR break down the current RFI into a few key areas – for example, the supply chain IT control tower concept, government procurement, transportation/warehousing, stockpile technologies, inventory buildup and shelf life – to focus the discussion and enhance the quality of responses among the specific stakeholders who can best discuss and develop an approach to the specific supply chain. The SNS could evaluate adoption of an ongoing life cycle strategy for supply management and use which targets replenishing the stockpile and using the supplies from the stockpile on an ongoing

basis regardless of whether an emergency occurs. This keeps the inventory technologically up to date and within appropriate shelf life. An ongoing annual review of the supplies will avoid wasteful buildup of inventory by multiple private parties and the government.

Finally, as the government pursues reform to the SNS, it is important to recognize the value of the global nature of medical device supply chains and how they have served to create resiliency, diversity and agility across the value chain. Sourcing materials, inputs and assembly where necessary also supports US medical technology manufacturers ability to be cost competitive and focused R&D and innovation. It is important note that two-thirds of all medical technology used in the U.S. is manufactured domestically. The remaining one-third is imported. Our largest source of imported products is the European Union (12.5 percent of overall consumption). Imports from Mexico account for just over five percent of total medical device usage, whereas China accounts for just 3.3 percent.

### **Specific Comments:**

**Inventory:** As the government reviews medical supplies and technologies for their suitability for the SNS, it should account for advances in science and technology as we learn more about COVID-19. Some technologies may become obsolete while others needed to be added for consideration. There should be a mechanism to consult with the private sector on advances in medical technology as it pertains to the SNS. Furthermore, an emergency with a rapid medical supply depletion requires a SNS structure that allows for refurbishing on an ongoing basis during non-emergencies and ongoing communications regarding technologies and needs. Supplies could be transitioned for use prior to expiration since an inventory buildup for unlimited amount of time may not be possible due to the shelf life of the supply. These factors need to be supply specific and account for the unique factors including changing technology. A series of town hall meetings as discussed above will allow for the development of supply specific channels which would more proactively address the needs.

**Ethylene Oxide (EtO or EO):** Ethylene Oxide (EO) is a colorless gas used in the sterilization of a vast number of medical devices including drapes, gowns, respirators and catheters. As the government looks at regulatory policies to support domestic supply of these kinds of technologies for the SNS, regulatory clarity around the use of EO and reasonable standards for usage will be essential.

**Shelf Life:** Building on The Shelf Life Extension Program, managed by DOD and FDA, the government could also consider a mechanism where any goods – finished or component – can be introduced by the government into commerce before their expiration dates. The proceeds could be used to replenish supply so that what's on the shelf is always within dating parameters. In addition, the SNS should have a mechanism to track inventory that is or will soon become obsolete and “swap” supplies that are close to end of life. This would eliminate the need to test and determine if the materials are still efficacious.

**In vitro Diagnostics (IVD):** The SNS should have adequate supply of diagnostic testing equipment, materials, and supplies – as it is critical to have the ability to rapidly test and diagnose patients who are sick or have been exposed to a pathogen. While it is not possible to

stockpile diagnostic tests for an unknown pathogen, certain tests can be stockpiled that can help rule out other infections. For example, annually, the stockpile could ensure it has flu tests available to rule out flu if a new pathogen causes similar respiratory symptoms. We recommend stockpiling the equipment necessary to process IVD tests – such as test instruments, analyzers and other capital equipment – to rapidly scale up diagnostic testing infrastructure and help to ensure prompt testing of samples in communities that may not have an existing lab or testing infrastructure. In addition, medical supplies used in the collection, transport and processing of IVD tests should be considered for the SNS. These include swabs, collection tubes, lancets, transport medium/tubes, and reagents such as DNA/RNA extraction kits, which are generally not specific to a particular test or pathogen.

**Ventilators:** The SNS should include a range of devices that can provide ventilation support for patients with respiratory syndromes specific to COVID-19. Access to critical care ventilators has been critical to the COVID-19 response and as those resources became stretched, alternative ventilation options such as non-invasive ventilation (NIV) bi-level and CPAP therapy were crucial to stabilize or sustain patients who required respiratory support. Studies have demonstrated that COVID-19 patients with less-severe respiratory distress could benefit from non-invasive ventilation therapy, thus freeing up more invasive ventilation devices for critically ill patients. As governments and health administrations around the world responded to the global demand spike for ventilators, many issued guidance documents on the use of bilevel or BiPAP devices that deliver NIV in patients with confirmed or suspected COVID-19. Moving forward, as the country reopens and braces for a potential second wave or surge in cases, it will be important to support patients into the sub-acute or out-of-hospital care environments on non-invasive ventilation devices that are already used in millions of homes every day. Additionally, the government should ensure it is prepared to support the various maintenance requirements of the ventilators in the SNS.

**Data Sharing:** Significant data sharing between the public and private sector underpins a number of the objectives in the RFI including creating visibility about inventory levels, distribution flows, epidemiological and disease state trends, demand forecasting and distribution. Given that much of this information could include sensitive data such as IP, trade secrets and other competitive information, there should be clear communication and guidance about how this information would be solicited, secured, shared and otherwise utilized.

**Transport:** AdvaMed's COVID-19 Supply Chain Task Force has identified transport disruptions as a leading barrier to delivering medical supplies to end users. With 3000 passenger airplanes in the United States grounded, and air travel down by 95%, there is a severe shortage in cargo capacity to transport medical supplies that in ordinary times rely heavily on passenger airline belly space. While industry is working with FAA and other relevant authorities to create additional capacity, we expect this issue to persist as it will take several years for passenger travel to resume to normal levels. Cargo transport – whether it's by passenger airlines, cargo freight, shipping or trucking – is a persistent concern that will drive up costs and continue to create bottlenecks as the pandemic continues in the U.S. and around the globe.

**Re-opening and vaccination:** Reforms to the SNS should take into consideration the PPE and medical supplies – including diagnostics tests - necessary to prepare for subsequent waves of the

virus that may occur as states reopen and also as we move into colder weather. The government should also begin preparing for and envisioning the investments and infrastructure necessary to provide vaccinations on a mass scale. We are concerned that manufacturing capacity for injection devices (i.e. needles and syringes) is not being addressed alongside vaccine development. COVID-19 vaccines under development will involve at least one skin injection (a second dose may also be required) with specific device requirements for intramuscular injections that current stockpiles are not able to service and adequate quantities of these products may not be readily available. The government needs to invest today to build additional capacity and initiate inventory stockpiling that will be needed to support the anticipated demand as soon as a viable vaccine is available.

**Additional technologies:** AdvaMed recommends that HHS/ASPR consider the following technologies for inclusion in the SNS:

- **Portable ultrasound, X-ray and isolated CT:** A consideration, particularly for highly transmissible lower respiratory infections caused by novel pathogens, is reducing the movement of positive or likely positive patients between departments in hospitals. Supporting an infrastructure that enables isolation is important. However, physicians often require imaging, which is performed in a radiology suite and is almost always located in a different part of the hospital, to inform diagnosis and treatment decisions. Stockpiling mobile imaging platforms such as handheld ultrasounds, mobile X-ray and CT for the purposes of deploying in the event of a COVID-like pandemic would enable more facilities to effectively isolate their patient populations.
- **Hospital Infrastructure:** A surge of patients associated with mass casualty events will strain the capital and disposable infrastructure of the acute care and intensive care units. With COVID-19, ventilators and PPE are both well-known to be in high demand. However, our members also experienced high demand for certain capital equipment and patient care disposables. The SNS should be equipped to support a broad range of products such as low-cost hospital beds that ship and store flat and patient care disposables such as oral care and urine management. The PPE listed in the strategy is undoubtedly critical to the SNS stockpile, but we also encourage HHS/ASPR to consider additional categories of PPE, such as a patient cover, that will add an additional physical barrier between the patient and caregiver. Including additional categories of PPE in the stockpile will allow for extra layers of PPE to be deployed quickly as a public health emergency is emerging.
- **Distancing Technologies:** Certain procedures commonly conducted on COVID-19 patients, such as CPR, intubation, and extubation are known to spread potentially infectious particulates. HHS/ASPR should consider for the stockpile, certain emergency medical equipment that helps create physical distance between healthcare providers and these potentially infectious particulates, or reduces the number of staff necessary, when performing these procedures (i.e. remote compression devices).