



AdvaMed

Advanced Medical Technology Association

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March 24, 2020

The Honorable Peter T. Gaynor
Administrator
Federal Emergency Management Agency
500 C Street SW
Washington, DC 20024

RE: Recommendation to Centralize Procurement and Allocation Decision-making of Ventilators

Dear Administrator Gaynor:

I write to you on behalf of the Advanced Medical Technology Association (AdvaMed). Many of our members are manufacturers of medical devices that are critical in the diagnosis and treatment of Covid-19, including ventilators, diagnostic tests, and other devices. We are well aware of the Administration's efforts to encourage industry to increase the production of products that are desperately needed to contain the virus and treat its victims. I will be communicating with you regarding a range of products, but the focus of this letter concerns ventilators.

Our membership includes major manufacturers of ventilators for use by patients in the United States. Their products have been subjected to rigorous review by the Food and Drug Administration for safety and effectiveness. They are the finest in the world. I cannot stress enough that the limitations on supplying ventilators are not because of decisions by these companies to produce fewer than they can. They are trying to produce as many ventilators as possible, including significant production increases. However, they are facing unprecedented demand for these complex products from health care providers all over the United States and the world.

Regarding the distribution of devices, there are two fundamental challenges. First, there are problems in allocating devices to health care providers who need them most. Many health care providers, as well as state and local governments, are trying to buy ventilators. Some of these potential purchasers should have a higher priority than others based on the acuity of patient needs in their areas. It is difficult for manufacturers to establish these priorities. We would appreciate the Administration's leadership and the advice of clinical and other experts within the Administration in deciding how to allocate these products in the most effective way.

Second, it is difficult in many cases to determine which source of products – a particular manufacturer, the Strategic National Stockpile, or other sources of inventory – can most efficiently provide products to certain users. These decisions can most effectively be made by a single federal coordinating entity that has information about possible sources of devices and the needs of individual users.





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We believe the most effective way to address these allocation issues is for the Administration to designate a lead agency, such as FEMA, to oversee these allocation decisions with the active input of clinical experts, including the CDC, and other stakeholders, including members of the health care community, patient advocacy groups, and industry. Manufacturers of ventilators would then commit to supply their production of these products for the U.S. to the Strategic National Stockpile, which would be distributed by or under the direction of FEMA or whatever lead agency is designated. Manufacturers would provide support to users of the distributed devices in installation, servicing, and training of appropriate employees in the use of the devices.

I welcome any opportunity to facilitate the advancement of a centralized acquisition and allocation framework or to dialogue on alternatives that you may be considering. Thank you for your time and consideration. I look forward to communicating with you further on our recommendations. Please do not hesitate to contact me at (202) 783-8700 or SWhitaker@advamed.org with any questions or concerns.

Sincerely,

Scott Whitaker

cc: The Honorable Michael R. Pence, The Vice President
The Honorable Alex M. Azar II, Secretary, U.S. Department of Health and Human Services