Congress of the United States

Washington, DC 20515

January 9, 2024

Hon. Shereef Elnahal, M.D.
Under Secretary for Health
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20004

Dear Dr. Elnahal:

We write to express our concern with the potential risk to veterans' health care posed by two proposed regulations issued by the Environmental Protection Agency (EPA) related to ethylene oxide (EtO). EtO is a gas used to sterilize nearly half of all medical devices, many of which could not be sterilized by any other available method. The Advanced Medical Technology Association projects that "if the proposals are finalized as written, the United States will see a massive interruption in patient care and access because of a 30 percent to 50 percent reduction in sterilization capacity for life-saving devices."[1]

This could have a significant impact on the ability of the Veterans Health Administration (VHA) to procure a substantial number of sterile medical devices. This is because the United States lacks sufficient sterilization capacity to address any surge in demand likely to be caused by facilities shutting down for upgrades or being closed permanently due to the cost of compliance with stringent new standards.

In response to a request for information from the EPA regarding the impact on medical devices, the Food and Drug Administration expressed significant concern about the implications for patients:

Without EtO, there would be a significant sterilization shortfall with no commensurate sterilization alternative available. Furthermore, shortages of a variety of critical medical devices would likely be imminent. Shortages stemming from a lack of EtO would have significant impacts on patient health and access to critical medical devices and patient care.[2]

Regulation is also imminent – one of these regulations must be in place by March 1, 2024, due to a consent decree signed by the EPA.

Given the urgency of this situation, we request your response to the below questions regarding VHA's preparation for a significant disruption to and/or reduction of U.S. sterilization capacity for medical devices:

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[1] https://www.advamed.org/industry-updates/news/advamed-epa-proposals-create-significant-risk-of-a-healthcare-crisis/

[2] https://www.regulations.gov/document/EPA-HQ-OPP-2013-0244-0049

1. Has the VHA studied the impact that reduced U.S. sterilization capacity could have on its ability to procure adequate supplies of sterile medical devices to treat the veterans under its care?

2. Has the VHA produced any written analysis of these impacts and/or possible strategies for mitigation?

3. Has the VHA communicated with the EPA, FDA, or the Office of Management and Budget regarding the impact such regulations would have on veterans' access to care?

Thank you for your service to our nation's veterans. We look forward to your prompt responses to this time-sensitive request.

Sincerely,

Mariannette Miller-Meeks,
M.D.
Member of Congress

Gregory F. Murphy, M.D.
Member of Congress

Derrick Van Orden
Member of Congress

cc: Michael Parrish
Chief Acquisition Officer and Principal Executive Director
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