Senator Chuck Schumer
Senate Majority Leader
Washington, DC 20510

Senator Mitch McConnell
Senate Republican Leader
Washington, DC 20510

The Honorable Michael Johnson
Speaker of the House
Washington, DC 20515

The Honorable Hakeem Jeffries
House Democratic Leader
Washington, DC 20515

February 23, 2024

Dear Majority Leader Schumer, Speaker Johnson, Leader McConnell, and Leader Jeffries:

The Health Industry Distributors Association (HIDA) represents 118 medical product distribution companies operating 500+ distribution centers nationwide. HIDA members deliver medical products and supplies, manage logistics, and offer customer services to virtually every healthcare provider. We are writing to urge Congress to support policies that will sustain the essential supply of sterile medical products available to patients.

Sterilized medical products are critical to healthcare. Medical devices are composed of many different types of materials that can be damaged if exposed to the wrong type of sterilization. For example, radiation can make plastics brittle, steam can damage electronics, and heat can melt acrylics. Poor or incomplete sterilization can lead to transmission of infectious diseases or compromised patient health. EPA stated in the Federal Register, "Commercial sterilization facilities play a vital role in maintaining an adequate supply of medical devices," and about 50% of all medical devices are sterilized with EtO. This amounts to more than 20 billion devices annually.

For many medical devices, EtO is currently the only sterilization method that does not damage a device during the sterilization process. It is often the most effective sterilizing agent for devices that have many packaging layers or hard-to-reach areas.

On November 3, 2023, the House passed H.R. 4821, the Department of the Interior, Environment, and Related Agencies Appropriations Act for Fiscal Year 2024. HIDA supports accompanying report language included in H.R. 4821 which would prohibit funding to issue regulations on Ethylene Oxide (EtO) emissions until the Food and Drug Administration (FDA) certifies that such regulations will not adversely impact the availability of sterile medical products.

HIDA appreciates the Environmental Protection Agency's (EPA's) commitment to addressing EtO risk using the best science and regulatory tools available under the law to protect community members and employees. Healthcare distributors also value and want to protect public health, and to do so they must deliver sterile, critical medical products to providers without interruption in the supply chain. Regulatory

policies that limit or abolish the use of EtO as a sterilization agent would have a profound negative effect on healthcare providers and patients.

The EtO regulations currently proposed, when combined with insufficient resources necessary for compliance and the unrealistic timeline to comply, would force commercial sterilization facilities that use EtO to either:

- Reduce production, resulting in backorders of essential medical products, while they install the required EtO controls;
- Move sterilization operations overseas, increasing uncertainty in the availability of medical products; or
- Permanently shut down, further impairing the healthcare supply chain.

For these reasons, we urge Congress to include the House-passed EtO language from H.R. 4821 in the next appropriations vehicle. Thank you for your leadership on this and all issues impacting healthcare distributors. If you should have any questions, please contact me at dibitetto@hida.org or learn more here.

Sincerely,

Kathryn DiBitetto
Vice President, Congressional Relations
Health Industry Distributors Association (HIDA)