Good afternoon, my name is Josh Babb. I serve as the Director of Government Affairs for the Health Industry Distributors Association (HIDA).

Thank you to the FDA and this Advisory Committee for the opportunity to address you on this important topic.

HIDA is the trade association representing medical products distributors. Approximately 600 distribution centers nationwide, HIDA members distribute the full range of medical products essential to every day medical services and procedures. These range from surgical kits, to catheters, as well as gauze and gloves. Distributors' customers include over 200,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the country. They also serve the healthcare facilities of numerous federal agencies such as the Veterans Administration and the United States military.

We recognize and appreciate the importance of environmental, public health and other factors with regard to the use of EtO for medical products. My comments today are from the perspective of the medical products supply chain supporting the nation's providers.

It goes without saying: sterilized medical products are mission critical to healthcare, and one that all facets of the industry are concerned about.

EtO is used because many products cannot tolerate other sterilization procedures. Today, more than 50% of all medical devices are sterilized using EtO - upwards of 20 billion devices annually. As is recognized by the FDA, there is no viable alternative currently available to replace EtO sterilization. Should regulatory policy or actions regarding the use of EtO affect overall sterilization capacity in the U.S., the impact on healthcare providers and patients would be profound.

For this reason, HIDA recommends a thoughtful approach that considers the impact on the delivery of healthcare nationwide. Any changes to EtO policies must include a realistic and feasible plan to anticipate and address any potential product disruptions.

Product Shortages

It is important for the Committee to understand that disruption at a single sterilization facility can have a magnified impact across the country and across all healthcare settings. Devices sterilized in one facility often support healthcare providers and patients in all 50 states.

Examples of these essential products include catheters, surgical kits and the ports used for delivering life-saving cancer treatments.

For example, a single facility in Georgia sterilizes 50% of the U.S. catheter market. A single facility in Illinois sterilizes 18-20% of the U.S. market of surgical kits used every day in hospitals for both routine and emergency procedures.

In FDA's recent statement on the issue, it was recognized restrictions on EtO use "ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care." Previous experience has also shown that a shortage in one product category can deplete adjacent product categories as providers adjust to meet their commitments to their communities.

Patient Access

These products ensure quality healthcare for millions of patients every day. These products ensure quality healthcare for millions of patients every day. Industry data indicates that over 1 million urinary catheters are used each month across all healthcare provider settings. Many millions more are used in the home setting. Access to sterilized catheters improves outcomes, manages infection rates, avoids hospitalizations and provides dignity and comfort to patients. These positive outcomes would be diminished if the supply chain for these critical products is disrupted.

EtO-sterilized surgical kits are delivered to operating rooms with the full range of products customized for a particular procedure. A disruption to surgical kit supply has the potential to impact the millions of surgical procedures in hospitals, surgery centers, and doctor's offices each year.

Realistic and Feasible Timeline Necessary

If EtO use is altered by regulatory shifts or legal decision, there must be a realistic plan - including a feasible timeline in place that addresses the significant challenges that would be created for healthcare. Without this consideration, the disruption to the provision of healthcare and the supply chain would be immediate and significant.

Contract sterilization facilities support multiple device manufacturers, which all have unique specifications for the sterilization of their devices. Changes in sterilization policies or methods

will require those specific processes to be altered and re-validated to ensure patient care is not compromised. An additional factor is the sheer number of devices that will be impacted.

For the reasons above, HIDA strongly urges caution and collaboration when considering the use of EtO for medical device sterilization. The nation's providers and patients need assurance that access to critical medical devices will not be compromised.

We urge FDA to continue to work closely with HIDA and the rest of our industry partners to ensure that the healthcare supply chain continues to provide safe products to our customers and the patients they serve.

We appreciate the FDA for convening this meeting and the opportunity to share our thoughts.

I am happy to provide any additional information you need and answer any questions you may have.