Congress of the United States

Washington, DC 20510

April 11, 2019

The Honorable Norman E. (Ned) Sharpless
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

We write today regarding ethylene oxide (EtO)—a known carcinogen that is widely used to sterilize medical devices nationwide—to get a better understanding about what actions the Food and Drug Administration (FDA) has taken, or will be taking, to examine and evaluate alternate, non-cancer causing sterilization methods for use in the United States.

As you are aware, the Sterigenics facility in Willowbrook, Illinois, is currently under a Seal Order, prohibiting them from using EtO to sterilize medical devices. This decision by the State of Illinois was made after the U.S. Environmental Protection Agency (EPA) found that the facility was emitting hazardous levels of EtO into the surrounding community. Additionally, a recent Illinois Department of Public Health (IDPH) report found that certain types of cancer linked to EtO exposure were higher in the Willowbrook community than elsewhere in the state. Specifically, when looking at the neighborhoods near the Sterigenics facility, the report found higher rates of Hodgkin's lymphoma in women, pediatric lymphoma in girls, as well as ovarian, breast, and pancreatic cancers.

As the toxicity of EtO is further examined, it is vitally important that the FDA begin making contingency plans, in the event other medical device sterilization facilities are shut down. We understand, and appreciate, that the FDA has actively been monitoring the Sterigenics situation and has been working closely with medical device manufacturers to ensure no supply chain disruptions in Illinois or nationwide. However, as we move forward and hopefully get a more complete understanding of the scope and impact that EtO emissions may be having on communities nationwide, it is imperative that FDA be ready in the event other facilities are similarly issued Seal Orders. The last thing we need—on top of the potential public health crisis created by high EtO emissions into communities—is a public health crisis involving shortages of medical devices at our nation's hospitals and surgical centers.

Further, part of FDA's contingency plans must involve immediately examining whether there are safer, non-cancer causing sterilization methods that can be used in the place of EtO. Approximately 50 percent of sterilized medical devices on the market today use EtO, but questions remain about whether or not there are effective alternate sterilization options available for these devices. Last November, we wrote a letter to FDA, encouraging your agency to "begin investigating alternatives to the EtO sterilization process and prioritize swift adoption of safer

methods and substances." We are curious to know if FDA has begun working with medical device companies to explore other, safer alternatives to EtO. If not, we would encourage you to do so immediately and without further delay.

It is imperative that our nation's medical devices are safe and sterile, but it is equally imperative that the methods used to sterilize those devices are not poisoning our air and causing cancer in our communities. We appreciate your timely attention to this issue and look forward to your response.

Sincerely,

Richard J. Durbin
United States Senator

Tammy Duckworth
United States Senator

Daniel W. Lipinski
United States Representative

Bradley S. Schneider
United States Representative

Lauren Underwood
United States Representative