

**Congress of the United States**  
**Washington, DC 20515**

April 22, 2019

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

Dear Acting Commissioner Sharpless:

We write today to inquire about the actions the Food and Drug Administration (FDA) has taken, or will be taking, to examine and evaluate alternatives to ethylene oxide (EtO) sterilization methods for use in the United States and to encourage you to continue to work with medical device companies to explore other, safer alternatives to EtO without delay.

Approximately 50 percent of sterilized medical devices on the market today use EtO which has recently been classified as a known carcinogen. 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 potentially hazardous levels of EtO into the surrounding community. 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. Given that there are some materials used in medical devices for which EtO may currently be the only method that properly sterilizes the devices, we urge the FDA to not only ensure contingency plans are in place to prevent disruption to the medical supply chain that would endanger patient safety, but to immediately examine whether there are safer, non-carcinogenic sterilization methods that can be used in the place of EtO.

It is imperative that our nation's medical devices are safe and sterile, and it is equally imperative that the methods used to sterilize those devices are safe for the workers sterilizing our nation's medical equipment as well as the communities that are home to these facilities. We appreciate your timely attention to this issue and look forward to your response.

Sincerely,



Bill Foster  
Member of Congress



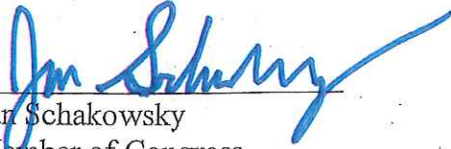
Sean Casten  
Member of Congress



Bradley S. Schneider  
Member of Congress



Raja Krishnamoorthi  
Member of Congress



Jan Schakowsky  
Member of Congress



Bobby L. Rush  
Member of Congress



Mike Quigley  
Member of Congress



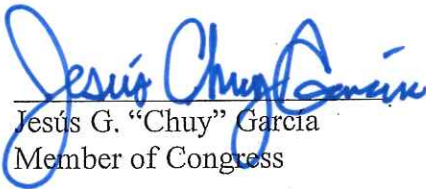
Cheri Bustos  
Member of Congress



Danny K. Davis  
Member of Congress



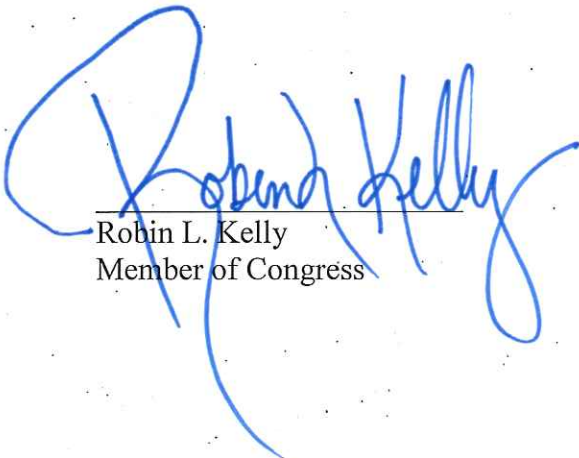
Daniel W. Lipinski  
Member of Congress



Jesús G. "Chuy" García  
Member of Congress



Lauren Underwood  
Member of Congress



Robin L. Kelly  
Member of Congress