

Congress of the United States

Washington, DC 20510

November 20, 2018

VIA ELECTRONIC DELIVERY

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We are writing to request that the U.S. Food and Drug Administration (FDA) convene an interagency task force to examine sterilization alternatives to ethylene oxide (EtO), a known carcinogen that is used at facilities and hospitals to sterilize medical equipment.

The public health threat of EtO is real. In June 2018, the Agency for Toxic Substances and Disease Registry (ATSDR) published a report indicating that the community in Willowbrook, Illinois, faces an increased cancer risk as a result of a nearby facility that uses EtO to sterilize medical equipment. However, our concern is not limited to Illinois. There are additional similar facilities throughout the United States that may be threatening other communities.

The U.S. Environmental Protection Agency's (EPA) failure to protect the public health by effectively updating its EtO permitting regulations made the problem worse. Despite the troubling ATSDR report, the Willowbrook facility technically was apparently in compliance with EPA's ineffective permitting requirements. Yet, even if EPA strengthens its regulations, the reality will remain that even at low levels, EtO is dangerous to public health.

That is why it is critical that FDA begin investigating alternatives to the EtO sterilization process and prioritize swift adoption of safer methods and substances. Americans should not be forced to choose between sterile medical equipment and increased cancer risks. We are hopeful that the dedicated men and women of FDA and throughout the scientific community, can work together to develop a safer alternative method of sterilizing equipment.

Sincerely,



Tammy Duckworth
United States Senator



Richard J. Durbin
United States Senator



Bradley S. Schneider
United States Representative



Bill Foster
United States Representative