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Title: Resolve the Unintended Consequences of the Ethylene Oxide Sterilization Shutdown at the Illinois Sterigenics Plant

Introduced by: James Szocik, MD, for the Washtenaw County Delegation

Original Author: James Szocik, MD

Referred to: Reference Committee D

House Action: **APPROVED**

Whereas, ethylene oxide is used in hospital sterilization of surgical equipment and plastic devices that cannot be sterilized by steam, and

Whereas, the Environmental Protection Agency (EPA) has stated that the weight of evidence from epidemiological studies and supporting information is sufficient to conclude that ethylene oxide is carcinogenic to humans' and

Whereas, due to these potential adverse health effects, the EPA shut down the use of ethylene oxide at the Sterigenics plant in Illinois due to excessive emissions, and

Whereas, ethylene oxide is currently the only Food and Drug Administration-approved method to fumigate certain medical equipment used in surgeries and other medical procedures, and

Whereas, the FDA believes that more than 100 medtech manufacturers and hundreds of devices may be affected by the shutdown, including approximately 159 products manufactured by Teleflex Medical Incorporated, and

Whereas this ethylene oxide ban has created the unintended consequence of supply shortages critical for patient care in the state of Michigan, therefore be it

RESOLVED: That MSMS send a letter to the Environmental Protection Agency asking that the safe operation and required mitigation to the ethylene oxide sterilization process at the Sterigenics plant be made a priority while simultaneously ensuring that other sites are given the ability to make up the shortfall; and be it further

RESOLVED: That MSMS send a letter to the American Medical Association and the Illinois Medical Association asking that they also petition the EPA to ensure that the ethylene oxide sterilization shutdown does not decrease the availability of critical and lifesaving procedures for patients across the area served by Sterigenics.

WAYS AND MEANS COMMITTEE FISCAL NOTE: \$1,000 or more as this resolution will require additional research and drafting of communications.

CONFLICT OF INTEREST STATEMENT:
I have the following conflict of interest to disclose:
James Szocik, MD is employed by Michigan Medicine, which receives federal funding from Medicaid, Medicare, and for resident training, as well as multiple private insurance agencies. Dr. Szocik has consulting in the past with MPRO, a peer-review organization.

Relevant MSMS Policy:

Policy Statement of Environmental Pollution

MSMS supports efforts to improve environmental health. MSMS supports all agencies charged with the control of environmental pollution. (Prior to 1990)

- Edited 1998
- Reaffirmed (Res35-05A)
- Reaffirmed (Res02-16)

Relevant AMA Policy:

Clean Air H-135.991

(1) The AMA supports setting the national primary and secondary ambient air quality standards at the level necessary to protect the public health. Establishing such standards at the level necessary to protect the public health. Establishing such standards at a level "allowing an adequate margin of safety," as provided in current law, should be maintained, but more scientific research should be conducted on the health effects of the standards currently set by the EPA.

(2) The AMA supports continued protection of certain geographic areas (i.e., those with air quality better than the national standards) from significant quality deterioration by requiring strict, but reasonable, emission limitations for new sources.

(3) The AMA endorses a more effective hazardous pollutant program to allow for efficient control of serious health hazards posed by airborne toxic pollutants.

(4) The AMA believes that more research is needed on the causes and effects of acid rain, and that the procedures to control pollution from another state need to be improved.

(5) The AMA believes that attaining the national ambient air quality standards for nitrogen oxides and carbon monoxide is necessary for the long-term benefit of the public health. Emission limitations for motor vehicles should be supported as a long-term goal until appropriate peer-reviewed scientific data demonstrate that the limitations are not required to protect the public health.

Late Resolution Information:

Could the resolution have been submitted before the 45-day deadline?

No, The public was not made aware of the closure and its impact on the supply of critical health care commodities, specifically endotracheal tubes, until the letter from Teleflex dated March 6, 2019 was circulated. The closure is likely to last for months, threatening the health of residents of Michigan due to lack of supplies for the remainder of 2019.

Did new developments after the dead line justify the acceptance of the resolution?

Yes, TEXT OF TELEFLEX LETTER March 6, 2019 Dear Valued Customer: Teleflex Medical Incorporated was recently notified that the Illinois Environmental Protection Agency issued an order February 15, 2019 to stop the Sterigenics facility in Willowbrook, Illinois from sterilizing medical and other products using ethylene oxide. The FDA believes that more than 100 medtech manufacturers and hundreds of devices may be affected by the shutdown. Approximately 159 products manufactured by Teleflex Medical Incorporated were sterilized at Sterigenics Willowbrook facility, which is less than 1% of the product codes we offer to customers. Below are the actions we are taking as a result of the Willowbrook facility shutdown: 1. Managing existing inventory to minimize customer impact 2. Actively exploring alternative locations for sterilization of the impacted codes 3. Increasing production, where necessary, of substitute products As information becomes available we will provide additional details. At Teleflex, people are at the center of all we do. Situations like this are no different. The health and safety of our employees, customers and communities are our highest priority. Please know that our team members will continue to work together in servicing healthcare providers to the very best of our ability so that Teleflex products are there when you need them. Thank you for your continued support. Sincerely, Ed Ed Weidner VP, Customer Experience and Commercial Operations Teleflex

Were there extenuating circumstances?

No

Are there any other resolutions that cover the same logic?

No

Sources:

1. <https://www.chicagotribune.com/news/local/breaking/ct-met-sterigenics-hearing-20190220-story.html>
2. <https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update>
3. <https://www.usnews.com/news/best-states/illinois/articles/2019-02-06/epa-continues-to-study-illinois-sterigenics-plant-pollution>
4. [https://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/82E68A48EE8ED66685257BA600556607/\\$File/CARCINOGENICITY-OF-ETO-FOR-SAB-CAAC-REVIEW.PDF](https://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/82E68A48EE8ED66685257BA600556607/$File/CARCINOGENICITY-OF-ETO-FOR-SAB-CAAC-REVIEW.PDF)
5. <https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf>