United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

July 19, 2023

VIA ELECTRONIC TRANSMISSION

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Ave
Washington, D.C. 20500

Michael Regan
Administrator, Environmental Protection Agency
1200 Pennsylvania Ave
Washington, D.C. 20004

Dear President Biden and Administrator Regan:

I am alarmed at the reckless lack of coordination by the White House of its Executive Branch agencies and departments, which will result in American deaths in the name of addressing abstract environmental concerns.

In particular, I am concerned about recent actions by the Environmental Protection Agency (EPA) to limit the presence of ethylene oxide (EtO).[1] EtO is widely used to sterilize medical devices, with an estimated 50% of all devices and 95% of all surgical kits sterilized with EtO.[2] EtO is the only sterilizer available for certain devices that cannot be sterilized with heat or radiation (e.g. endoscopes, syringes, heart valves). Specifically, all devices that integrate flexible tubing and plastic polymers can only be sterilized using EtO.

The impact of EPA's proposals will be to shutter approximately half of all U.S. commercial sterilizers, decimating much of the medical device manufacturing industry in the United States, exacerbating and creating medical product shortages, increasing American reliance on foreign

[1] *Actions to Protect Workers and Communities from Ethylene Oxide (EtO) Risk*, Environmental Protection Agency (April 11, 2023), https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/actions-protect-workers-and-communities-ethylene-oxide-eto.
[2] *Id.*

suppliers, and costing American lives due to lack of access to critical medical supplies.[3] Abstract environmental harms identified by EPA pale in comparison to the widespread harm to patient health and safety that will be caused by EPA's proposals.

Despite the negative impact of this proposal, EPA has failed to show that reducing EtO use as a sterilizing agent would improve human health. Scientific studies show that communities co-located with sterilizing facilities do not have higher EtO levels than ambient air levels due to naturally occurring EtO.[4]

EPA's process for developing its proposals was nothing short of irresponsible. EPA failed to perform any cost analysis on the impact of the proposal for medical device sterilizers or point to any alternative sterilization method, despite insisting there are alternative solutions.[5] EPA also failed to address the numerous and serious concerns raised by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS), a sister department. As part of the regulatory process to publish these proposals, FDA provided official interagency feedback on the impact of EPA's proposals, including the feasibility of the strict 18-month implementation timeline. EPA, however, failed to integrate any of this feedback into the published proposed rule. As the federal government examines proposals to reduce medical product shortages and onshore more of the health care supply chain, EPA's proposals would only exacerbate these challenges.

EPA's failure to engage in rulemaking without considering interagency feedback is the latest in a series of actions by your administration to make policy proposals that impact the health care sector without consulting health care regulators.[6] To that end, I ask that you answer the following questions on a question-by-question basis by **August 11, 2023**:

1. What coordination between EPA and FDA did the White House and the Office of Management and Budget (OMB) conduct in the development of EPA's proposed rules?
    a. Why does the White House prioritize EPA's abstract environmental concerns over imminent patient health and safety impacts raised by FDA?
    b. What will the White House do to facilitate an improved final rule that will prevent the shuttering of medical device manufacturing in the United States and maintain American competitiveness?

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[3] *AdvaMed Outlines Four Key Priorities in Letter to President on Sterilization*, Advanced Medical Technology Association (January 19, 2023), https://www.advamed.org/industry-updates/news/advamed-outlines-four-key-priorities-in-letter-to-president-on-sterilization/.

[4] Patrick J. Sheehan et al., *Ethylene Oxide Exposure in U.S. Populations Residing Near Sterilization and Other Industrial Facilities: Context Based on Endogenous and Total Equivalent Concentration Exposures*, International Journal of Environmental Research and Public Health (Jan. 12, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7828163/pdf/ijerph-18-00607.pdf.

[5] *Regulation of Ethylene Oxide (EtO) Under the Federal Insecticide, Fungicide, and Rodenticide Act*, Environmental Protection Agency (May 24, 2023), https://www.epa.gov/ingredients-used-pesticide-products/regulation-ethylene-oxide-eto-under-federal-insecticide.

[6] *Letter to White House on shortage of research monkeys*, Senate Health, Education, Labor & Pensions Committee Minority (July 19, 2023)

c. EPA stated that medical device supply shortages would be a "whole of government" problem and that FDA would be responsible for the solution. Did EPA consult with FDA in advance of making this assertion to confirm its ability to address these issues?
d. Was the White House made aware of EPA's assertion before EPA issued the proposed rule?

2. FDA provided interagency comments to EPA on its proposal to limit EtO use as a sterilizer. Why were FDA's comments not addressed in the proposed rule? Please provide a justification for each of FDA's comments that were not addressed.

3. How did EPA decide upon its proposed EtO limits? Why did EPA not consider or adopt other guidelines, like those of the Texas Commission on Environmental Quality (TCEQ)? Has EPA engaged with independent scientific bodies, like the National Academies of Science and Medicine (NASEM), to do an analysis of appropriate limits? If so, please elaborate on that engagement and coordination. If not, why not?

4. Should the rule be finalized, what work has the White House done to ensure that a medical device shortage will not have a negative impact on readiness or response in the event of a national security issue?

5. How did EPA calculate the cost analysis for reducing EtO use? How does EPA support its assertion in the proposed NESHAP rule that the proposed limits are "achievable" without causing medical device shortages?

6. Has the White House evaluated medical device capacity reductions for sensitive populations such as community health centers, rural health centers, Indian Health Service facilities, and Department of Defense and Veterans Affairs health centers?

7. What studies did EPA use to measure the health harms related to EtO use in sterilizing facilities?

8. Has EPA studied projected adverse health risks due to medical supplies shortages? If so, what were EPA's findings? If not, why not?

9. What analysis did EPA conduct in analyzing the feasibility of an 18-month implementation timeline?
    a. EPA acknowledged that many facilities may need to go off-line during the compliance period. Did EPA conduct an estimate in capacity reduction during those off-line periods?

10. EPA listed alternative sterilizers for other impacted entities, such as museums and libraries. Did EPA perform a comparative analysis for medical sterilizers? If so, what were EPA's findings and why were they not included in the proposed rule?

11. EPA estimated that over 14,000 devices will need to undergo validation testing to set lower EtO levels for sterilization.[7] How did EPA come to this figure, considering over 20 billion medical devices used each year rely on EtO for sterilization?[8]

I look forward to your prompt response.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
United States Senator

Copy:

Dr. Robert Califf
Commissioner, U.S. Food and Drug Administration

[7] *Comment Letter to Environmental Protection Agency on National Emission Standards for Hazardous Air Pollutants: Commercial Ethylene Oxide Sterilization Technology Review & Ethylene Oxide Proposed Interim Registration Review Decision*, Medical Device Manufacturers Association (June 26, 2023), https://www.regulations.gov/comment/EPA-HQ-OPP-2013-0244-0092.

[8] *Statement on concerns with medical device availability due to certain sterilization facility closures*, Food and Drug Administration (October 25, 2019), https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures#:~:text=Because%20the%20number%20of%20ethylene,to%20take%20care%20of%20patients.