

January 23, 2024

Xavier Becerra
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

cc: Dr. Robert M. Califf, Commissioner, U.S. Food and Drug Administration (FDA); Dr. Jeffrey E. Shuren, Director of Center for Devices and Radiological Health, FDA

RE: Letter Urging the U.S. Department of Health and Human Services to ensure that the U.S. Food and Drug Administration Limits the Use of Ethylene Oxide as a Medical Device Sterilant and Requires Industry to Transition to Safer Alternatives

Dear Secretary Becerra,

The undersigned 507 scientists and public health experts are writing to urge the US Department of Health and Human Services (HHS) to ensure that the US Food and Drug Administration (FDA) takes swift action to limit the use of ethylene oxide as a medical device sterilant and to require the transition to safer alternatives for sterilization, as much as safely possible.

On April 11, 2023, the US Environmental Protection Agency (EPA) issued critical proposed regulations to limit emissions of ethylene oxide, a potent cancer-causing gas, in commercial sterilization facilities.¹ While these long-overdue regulations could yield significant reductions in ethylene oxide pollution in communities adjacent to these facilities, these emissions reductions will be not equitably distributed as Latine and Black populations will continue to live with significant exposure to ethylene oxide when compared to other population subgroups.² A February 2023 analysis by the Union of Concerned Scientists (UCS) found that nearly 14 million people live within five miles of these facilities, with more than 10,000 schools and childcare centers in the same area.³ UCS also found that the populations in close proximity to these facilities are disproportionately people of color, people with low income, and people who do not speak English as a first language. Furthermore, cancer risks attributable to toxic air pollutants were significantly greater in communities with sterilization facilities, and these risks were even higher in communities of color. A recent analysis also found that more than 90 percent of commercial sterilization facilities are in or within three miles of a census tract categorized as “disadvantaged” by the federal Climate and Economic Justice Screening tool.⁴

Even with the EPA’s proposed emissions reductions, people who live, work, and play near these facilities—many of whom were unknowingly exposed to ethylene oxide for decades—will continue to breathe this toxic chemical. Furthermore, even with stricter controls, workers at sterilization facilities and hospitals will still face exposure risks (and hospital emissions regulations have yet to be revised by EPA). Therefore, it is imperative for emissions reductions to be paired with meaningful efforts to reduce the use

¹ U.S. Environmental Protection Agency (EPA). “Proposal to Reduce Ethylene Oxide Emissions from Commercial Sterilization Facilities.” October 31, 2023, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/proposal-reduce-ethylene-oxide-emissions-commercial>

² Proposed Rule, National Emissions Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review. “Comment submitted by Earthjustice et al.” July 3, 2023, <https://www.regulations.gov/comment/EPA-HQ-OAR-2019-0178-0634>

³ Minovi, D. “Invisible Threat, Inequitable Impact: Communities Impacted by Cancer-Causing Ethylene Oxide Pollution.” Union of Concerned Scientists. February 2023, <https://www.ucsusa.org/resources/invisible-threat-inequitable-impact>

⁴ Data available upon request.

of ethylene oxide altogether **by requiring medical device manufacturers to use alternative sterilization methods** such hydrogen peroxide, while still ensuring the safety of medical devices. We recognize the importance of ensuring that medical products meet microbial limit standards; however, many medical devices that are currently sterilized with ethylene oxide could be safely sterilized with safer alternatives.

We acknowledge FDA’s efforts to “advance innovative ways to sterilize with lower levels of currently used agents, and employ new agents or alternatives;” however, we are concerned that these efforts have not yielded substantive changes to agency regulations. In 2019, the FDA announced two Innovation Challenges to “Identify New Sterilization Methods and Technologies”⁵ and “Reduce Ethylene Oxide Emissions.”⁶ Four years since these challenges were announced, there have been few updates from the FDA on the outcomes of these challenges or the alternative sterilization methods that are being evaluated. Furthermore, members of the public were given few, if any, opportunities to participate or engage in this process. The latest updates from the FDA’s Center for Devices and Radiological Health only announced that the International Standards Organization’s new standard for the use of low temperature vaporized hydrogen peroxide was added to the agency’s Recognized Consensus Standards database,⁷ and provided reporting guidance to manufacturers that voluntarily use this process.⁸ While it is important to advance efforts to encourage the use of hydrogen peroxide—which is less toxic to public and worker health and not a carcinogen—in sterilization, these actions are not enforceable and do not substantively reduce ethylene oxide use. As such, **we are requesting HHS to ensure that the FDA promptly communicates the latest developments of the Innovation Challenges and issue enforceable standards that limit the use of ethylene oxide and move medical device manufacturers to transition to safer alternative sterilization methods.**

Under HHS leadership, the FDA’s mission states that the agency is “responsible for protecting the public health by ensuring the safety, efficacy, and security of human [...] drugs, biological products, and medical devices...”⁹ Yet, the FDA allows about half of all sterile medical devices in the United States to be sterilized with ethylene oxide, a substance that ensures medical devices are safe for some, while causing devastating health effects for others.¹⁰

While the EPA is responsible for limiting pollution emissions from facilities that use toxic substances, FDA has the authority to require the use of safer alternatives that ensure there are no toxic emissions to begin with. The FDA’s obligation to ensure that medical devices are safe to use cannot only extend to the patients who benefit from the direct use of those devices but must also include the safety of those throughout the supply chain, including health care and sterilization facility workers, and people who live, work, and play near these facilities. There are already numerous studies documenting elevated cancer

⁵ U.S. Food and Drug Administration (FDA). “FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies.” November 25, 2019, <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies>

⁶ FDA. “FDA Innovation Challenge 2: Reduce Ethylene Oxide Emissions.” November 25, 2019. <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions>

⁷ FDA. “CDRH Announces New Standards Recognition to Support Innovation in Medical Device Sterilization.” July 24, 2023, <https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-new-standards-recognition-support-innovation-medical-device-sterilization>

⁸ FDA. “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile. January 2024, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>

⁹ FDA. “FDA Mission.” <https://www.fda.gov/about-fda/what-we-do#mission>

¹⁰ FDA. “Sterilization for Medical Devices.” <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices>

risks¹¹ and higher rates¹² of cancer associated with ethylene oxide exposure around sterilization facilities. HHS must use its authority to ensure that the FDA takes regulatory action to protect public health and increasingly limit the use of ethylene oxide in medical device sterilization whenever it is safely possible. Furthermore, it is critical to ensure that the FDA does not impede the EPA's efforts to adopt more protective emissions standards,¹³ and that all agencies under HHS leadership follow through on this administration's commitments to environmental justice.¹⁴

We thank you for considering our request.

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¹¹ EPA. "Evaluation of Inhalation Carcinogenicity of Ethylene Oxide (Final Report)." 2016, https://cfpub.epa.gov/ncea/iris_drafts/recorddisplay.cfm?deid=329730

¹² Texas Department of State Health Services. "Assessment of the Occurrence of Cancer, Laredo, Texas, 2006-2019." October 21, 2022, https://www.dshs.texas.gov/sites/default/files/CHI-ESTB/CSum%2022002_Full%20Report_Final.pdf

¹³ Reuter, E. "FDA: 'We have a very loud voice' on EtO." MedTechDive. October 16, 2023, <https://www.medtechdive.com/news/fda-eto-regulations-epa-medical-device-supply/696624/>

¹⁴ The White House. "Executive Order on Revitalizing Our Nation's Commitment to Environmental Justice for All." April 21, 2023, <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/21/executive-order-on-revitalizing-our-nations-commitment-to-environmental-justice-for-all/>

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