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## Deploy Rational Science-Based Policies for Medical Plant Sterilization

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Several medical supply sterilization plants have shut down during the past year because of unwarranted fearmongering about ethylene oxide (EtO), a gas used to sterilize medical equipment and for which there is no viable alternative. EtO became an issue after the U.S. Environmental Protection Agency (EPA) released a faulty analysis that vastly overstated the risks associated with EtO.<sup>1</sup> That led several states and localities to shut down several medical equipment sterilization plants.<sup>2</sup>

Those plant closures then led the Food and Drug Administration (FDA) to warn of likely shortages of medical supplies, which were realized when the COVID-19 outbreak greatly increased demand. Since then, a few plants have reopened to help generate supplies necessary to fight the virus, but federal regulators should ensure that these facilities remain open well into the future and that the policies and programs that created the unwarranted health scare are reversed.<sup>3</sup>

EtO is a clear gas naturally produced inside the human body. It is also naturally produced and released into the air from combustion, vegetation, manure, volcanic eruptions, waterlogged soil, and other sources. It has many valuable commercial applications, such as in the manufacture of shampoo, cleaners, antifreeze, and more.

Less than 1 percent of commercially produced EtO is used to sterilize more than 20 billion medical products—more than half of all sterile medical products in the United States.<sup>4</sup> The FDA notes that “ethylene oxide may be the only method that effectively sterilizes and does not damage the device.”<sup>5</sup> In other words, as FDA Commissioner of Food and Drugs Norman E. Sharpless explained last October, “this method is critical to our health care system and to the continued availability of safe, effective and high-quality medical devices.”<sup>6</sup>

EtO has been safely used for decades, and the tiny traces released from medical plant sterilization were understood to be inconsequential to human health. But the perception of the risk changed when an EPA research program known as the Integrated Risk Information System (IRIS) released a highly flawed assessment of EtO risks.<sup>7</sup>

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For the past couple of decades, the IRIS program has been under fire from the National Academy of Sciences,<sup>8</sup> lawmakers,<sup>9</sup> and others for producing faulty assessments.<sup>10</sup> The assumptions IRIS uses often vastly overestimate risks.<sup>11</sup>

In 2016, IRIS released a controversial “reference concentration”—an agency-determined safe level for people who continuously inhale the gas—for EtO at 0.1 parts per trillion or 0.0000001 parts per million.<sup>12</sup> By comparison, the Occupational Safety and Health Administration’s safety standard is one part per *million*, for workers exposed five days a week, eight-hours a day for decades.<sup>13</sup>

“Ethylene oxide is suddenly getting attention because an office within the EPA changed the way it calculated the amount it considers safe to breathe. No new science was used, just new math,” explains toxicologist Gail Charnley.<sup>14</sup> According to Charnley, the number is nearly 20,000 times lower than the amount produced naturally in the human body, 5,000 times lower than levels normally found in suburban air, and more than “5 million times more stringent than the scientific judgements underlying all other regulatory limits on ethylene oxide in the United States and worldwide.”<sup>15</sup>

Nonetheless, in a 2018 report on air quality, the EPA’s National Air Toxics Assessment (NATA) ran some models to estimate where air concentrations of the chemical might exceed IRIS’ 2016 reference concentration. In a fact sheet about the report, the EPA noted: “The 2014 NATA shows that several areas could have elevated cancer risks from long-term exposure to the chemical ethylene oxide. These elevated risks are largely driven by an EPA risk value that was updated in late 2016.”<sup>16</sup>

The NATA report set off a panic in communities located near medical equipment sterilization plants. In a series of articles, the *Chicago Tribune* developed a false narrative that the Trump administration was working to allow EtO emissions at levels that poison communities and cause cancer.<sup>17</sup> Such hype prompted some local activists to call for shutting down medical sterilization plants around the country.<sup>18</sup>

Since then, the EPA has collected data on the levels found outside these facilities, and despite much hype, the levels are not alarming. Charnley explains: “No doubt, scientific truths are desperately needed in the public dialogue. The most important truth being, there is no cancer threat from the tiny amounts of ethylene oxide released from these sterilization plants.”<sup>19</sup>

During 2019, several states and localities shut down medical supply sterilization plants because of fearmongering set off by the EPA’s flawed research.<sup>20</sup> The FDA issued repeated warnings last year—in March,<sup>21</sup> September,<sup>22</sup> and October<sup>23</sup>—that these closures could lead to shortages of medical supplies, which could become serious, particularly if a medical emergency were to arise.

In fact, long before we knew about COVID-19 there was a shortage of pediatric breathing tubes in April 2019, resulting from the closing of a sterilization plant in Willowbrook,

Illinois.<sup>24</sup> After that, another Illinois plant also closed, as well as facilities in Georgia and Michigan.<sup>25</sup>

Last November, as worries about shortages mounted, the FDA assembled an advisory meeting with a panel of experts from its Devices Advisory Committee at which participants expressed grave concerns.<sup>26</sup> The sterilization plant closures, explained San Juan Regional Medical Center physician Robert Burr, promises to produce a “major medical logistical failure”—and that was before the COVID-19 outbreak.<sup>27</sup>

Faced with the COVID-19 emergency, the FDA asked these companies to reopen plants to help deal with severe medical supply shortages—and threatened legal action against one local government to make it happen.<sup>28</sup> A facility in Cobb County, Georgia, which the county shut down in August 2019, won a court order on April 1 to reopen.<sup>29</sup> A plant in Waukegan, Illinois, which shut down voluntarily last December to upgrade emission controls, has also reopened.<sup>30</sup> The Willowbrook facility remains closed, and the company announced last year that the closure would be permanent.<sup>31</sup>

The reopening of these plants has proven critically important. When the Waukegan facility reopened, a company representative noted that it would sterilize 100,000 masks per day, in addition to other medical supplies.<sup>32</sup> Dr. Soumi Saha, the director of advocacy at Premier—a company involved in purchasing of medical equipment for health care providers—explained in *General Surgery News*:

“That’s opened up tremendous capacity in the U.S. to help sterilize PPE and other medical supplies that are being used to care for COVID-19 patients.” Ideally, that will continue, she added. “Our hope is the reopening of the facilities in Illinois and Georgia are not temporary, and that going forward, the FDA, EPA and CDC work together to collaboratively define acceptable ETO emissions and sterilization techniques, which will help ensure continued availability of sterile medical supplies.”<sup>33</sup>

Unfortunately, these facilities could be undermined in the future because of continued efforts to misinform the public about the risks. For example, on March 31 the EPA Inspector General (IG) issued a report that alleges that EPA officials failed to warn people of cancer risks associated with ethylene oxide (EtO) emissions from medical sterilization plants.<sup>34</sup> The IG’s allegations are based on the flawed IRIS assessment. They are now generating more unwarranted fears, prompting yet more activist groups to call for a ban on ethylene oxide.<sup>35</sup> These activists may be well meaning, but their recommendations are uninformed and threaten public health.

The bottom line is that the EPA IG report is irresponsible and dangerous. By calling on the EPA to sound false alarms in communities around the nation, we can expect more such dangerous and misguided activism, leading to more potential closures now and in the future. EPA officials have been working for more than a year with communities where these plants are located to address concerns and ensure emissions remain low. That may explain

why EPA Administrator Andrew Wheeler expressed dismay about the IG report and called for the office to rescind it.<sup>36</sup>

If COVID-19 teaches us anything, it is that we need to remain prepared for emergencies. Shutting down critical operations such as medical supply sterilization plants, without justification, is dangerous. Accordingly, the EPA and policy makers should:

- Not issue warnings to communities about EtO emissions, as recommended by the faulty IG report. Such warnings are not based on science, would be misleading, and would prompt unwarranted health scares and potentially counterproductive state regulations.
- Rescind the Integrated Risk Information System's Risk assessment for EtO and produce a more balanced reevaluation under scientific guidelines administered by the agency's Office of Pollution Prevention and Toxics as part of its statutorily defined mission to implement the Toxic Substances Control Act.
- Shut down the IRIS program and focus its risk assessment functions inside the Office of Pollution Prevention and Toxics.
- Urge the Inspector General's office to rescind its misleading report.
- Shut down the National Air Toxics Assessment, which has a history of spreading misinformation about air quality risks and promoting unbalanced and counterproductive policies.
- Preempt state efforts to shut down medical plant sterilization facilities that already meet agency emission standards.

## Notes

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<sup>2</sup> U.S. Food and Drug Administration, "Ethylene Oxide Sterilization Facility Updates," accessed April 23, 2020, <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates>.

<sup>3</sup> Angela Logomasini, "EPA Inspector General Report Could Exacerbate Medical Supply Shortages," OpenMarket, Competitive Enterprise Institute, April 3, 2020, <https://cei.org/blog/epa-inspector-general-report-could-exacerbate-medical-supply-shortages>.

<sup>4</sup> The Ethylene Oxide Sterilization Association, "Flawed Science and Modeling by EPA Result in Inappropriate Conclusions that Could Have Disastrous Adverse Public Health Impacts," September 18, 2018, <https://www.eosa.org/sites/default/files/2018-09/EOSA%20Position%20Paper%20-%20Flawed%20Science%202018-09.pdf>; "Ethylene Oxide," *IARC Monograph* Volume 97 (IARC, 2008), <https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100F-28.pdf>.

<sup>5</sup> U.S. Food and Drug Administration, "Ethylene Oxide Sterilization for Medical Devices," accessed April 23, 2020, <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices#why>.

<sup>6</sup> Norman E. Sharpless, "Statement on Concerns with Medical Device Availability Due to Certain Sterilization Facility Closures," FDA, October 25, 2019, <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures>.

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- <sup>9</sup> Erik Stokstad, "EPA's Evaluations of Chemicals Come Under Fire," *Science*, July 15, 2011, <https://www.sciencemag.org/news/2011/07/epas-evaluations-chemicals-come-under-fire>.
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- <sup>12</sup> Expressed as 5 x 10<sup>-3</sup> per µg/m<sup>3</sup> in "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Executive Summary, Integrated Risk Information System," December 2016, [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/subst/1025\\_summary.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf). The American Chemistry Council notes that 5 x 10<sup>-3</sup> per µg/m<sup>3</sup> is the same as .1 ppt in "Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment, American Chemistry Council, September 20, 2018, [https://www.epa.gov/sites/production/files/2018-10/documents/iqa\\_petition\\_eo-\\_sept\\_2018\\_0.pdf](https://www.epa.gov/sites/production/files/2018-10/documents/iqa_petition_eo-_sept_2018_0.pdf).
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<sup>28</sup> Carolyn Ryan, “Feds threaten action against Cobb County if it doesn’t expand sterilization order,” CBS46 Atlanta, March 27, 2020, [https://www.cbs46.com/news/feds-threaten-action-against-cobb-county-if-it-doesn-t/article\\_edb514a4-7092-11ea-acf9-a7546c2c92e0.html](https://www.cbs46.com/news/feds-threaten-action-against-cobb-county-if-it-doesn-t/article_edb514a4-7092-11ea-acf9-a7546c2c92e0.html).

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<sup>33</sup> Ibid.

<sup>34</sup> U.S. Environmental Protection Agency, Office of Inspector General, “Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns,” Report No. 20-N-0128, March 31, 2020, [https://www.epa.gov/sites/production/files/2020-03/documents/\\_epaig\\_20200331-20-n-0128\\_0.pdf](https://www.epa.gov/sites/production/files/2020-03/documents/_epaig_20200331-20-n-0128_0.pdf).

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<sup>36</sup> U.S. Environmental Protection Agency, “EPA Administrator Wheeler Responds to Office of Inspector General Report on Ethylene Oxide,” news release, March 31, 2020, <https://www.epa.gov/newsreleases/epa-administrator-wheeler-responds-office-inspector-general-report-ethylene-oxide>.