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## No Consensus: Patchwork Remedies and the Health Crisis Linked to Ethylene Oxide Medical Sterilization Facilities

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# No Consensus: Patchwork Remedies and the Health Crisis Linked to Ethylene Oxide Medical Sterilization Facilities

STACI L. VAZQUEZ<sup>1</sup>

*This article strives to provide an overview of the environmental health crisis surrounding medical sterilization facilities and examine the variety or “patchwork” of legal solutions involved. Part II of the article will discuss the dangers of ethylene oxide (EtO), how it is used for sterilization of medical equipment, and the health impacts that occur when emissions of the chemical are released into communities. Part III will explain how ethylene oxide is regulated, as well as the framework of federal, state, and local regulations. Part IV will demonstrate what happens when these mechanisms fail by discussing a recent environmental health crisis in Illinois. Part V will turn to the legal remedies for environmental pollution. It will discuss legislative action or the lack thereof, by individual states. It will also analyze issues involving federal agencies and their response to these issues. Further, it will address the problems that may occur given these agencies’ lack of consensus on how to address ethylene oxide and medical sterilization, demonstrated by the patchwork of legal remedies available through various levels of government.*

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## I. INTRODUCTION

The process of sterilizing medical equipment and devices is big business. In the United States, more than twenty billion devices sold each year are sterilized with a method that uses a chemical called ethylene oxide.<sup>2</sup> Facilities using the ethylene oxide method to sterilize medical equipment and devices are located throughout the nation.<sup>3</sup> In recent years, communities have discovered that these medical sterilization facilities have been emitting ethylene oxide into the environment, which has caused residents near the facilities to develop a variety of illnesses.<sup>4</sup> Most people believe that government oversight of these facilities and the chemicals they use, means that the facilities are safe and there is no cause for concern. Unfortunately, this is not always the case.

This Article strives to provide an overview of the environmental health crisis surrounding medical sterilization facilities and examine the variety or “patchwork” of legal solutions involved. Part II of the Article will discuss the dangers of ethylene oxide (EtO), how it is used for sterilization of medical equipment, and the health impacts that occur when emissions of the chemical are released into communities. Part III will explain how ethylene oxide is regulated, as well as the framework of federal, state, and local regulations. Part IV will demonstrate what happens when these mechanisms fail by discussing a recent environmental health crisis in Illinois. Part V will turn to the legal remedies for environmental pollution. It will discuss legislative action, or the lack thereof, by individual states. It will also analyze issues involving federal agencies and their response to these issues. Further, it will address the problems that may occur given these agencies’ lack of consensus on how to

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2. Norman E. Sharpless, *Statement on Concerns with Medical Device Availability Due to Certain Sterilization Facility Closures*, U.S. FOOD & DRUG ADMIN. (Oct. 25, 2019), <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures> [https://perma.cc/5K25-C55S].

3. See Michael Hawthorne, *More than Half a Million Americans Exposed to Toxic Air Pollution Face Cancer Risks Above EPA Guidelines*, CHI. TRIB. (July 25, 2019, 3:26 PM), <https://www.chicagotribune.com/news/environment/ct-ethylene-oxide-cancer-risks-toxic-communities-20190725-my4fm5lafhljpusnorznzlwpu-story.html> [https://perma.cc/K8YB-MBYR].

4. *Id.* See generally Kimberly Fornek, *Emissions from Willowbrook Company Could Be Harmful to Residents, Federal Report Says*, CHI. TRIB. (Aug. 27, 2018, 12:15 PM), <https://www.chicagotribune.com/suburbs/burr-ridge/ct-dbr-willowbrook-sterigenics-tl-0830-story.html> [https://perma.cc/L8ER-GTC2].

address ethylene oxide and medical sterilization, demonstrated by the patchwork of legal remedies available through various levels of government.

## II. ETHYLENE OXIDE MEDICAL STERILIZATION AND ITS HEALTH IMPACTS

This section will introduce ethylene oxide as well as how and why it is used in the process of sterilization of medical equipment and devices. It will also address its risks and benefits, including the risks to the communities surrounding the facilities.

### A. ETHYLENE OXIDE AND MEDICAL STERILIZATION

This section will introduce ethylene oxide, how it is used, and its risks and benefits. Ethylene oxide is a flammable, colorless gas, that is used, among other things, to sterilize medical equipment and other medical devices that cannot be sterilized by any other process.<sup>5</sup> Invented in 1925 by Lloyd Hall,<sup>6</sup> a well-known chemist, the ethylene oxide method of sterilization is used to sterilize about 50 percent of all medical equipment in the United States today.<sup>7</sup> In fact, “[f]or many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device during the sterilization process.”<sup>8</sup> The reason for this is because many of the instruments and equipment have multiple layers, small, hard to reach places, or they are made out of certain materials, such as plastic, resin, metals, or glass, which require it to be sterilized this way.<sup>9</sup>

### B. HEALTH IMPACTS OF ETHYLENE OXIDE

According to the Agency for Toxic Substances and Disease Registry, ethylene oxide is known to be not only a human carcinogen, but it also causes a myriad of other health related issues.<sup>10</sup> Ethylene oxide is absorbed quickly after inhalation, is water soluble, and can penetrate the skin.<sup>11</sup> Children are more susceptible to the effects of the gas because since they are smaller, their

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5. *Company Overview*, STERIGENICS (2019), <https://sterigenics.com/about-us/> [<https://perma.cc/65C2-37M6>].

6. *Id.*

7. *Ethylene Oxide Sterilization of Medical Devices*, U.S. FOOD & DRUG ADMIN. (Nov. 26, 2019), <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices> [<https://perma.cc/47VV-Y2U4>].

8. *Id.*

9. *Id.*

10. *Managing Hazardous Materials Incidents*, ATSDR (Oct. 21, 2014), <https://www.atsdr.cdc.gov/MHMI/mmg137.pdf> [<https://perma.cc/3UNR-UU6M>].

11. *Id.* at 1.

lungs have a greater surface area as compared to the rest of their body.<sup>12</sup> Additionally, being smaller in size, children are naturally closer to the ground where increased levels of ethylene oxide often reside so they inhale a greater amount of the toxin.<sup>13</sup>

Ethylene oxide causes cellular and tissue dysfunction, which often leads to cancer.<sup>14</sup> In fact, the U.S. Environmental Protection Agency (EPA) recently determined that ethylene oxide is the cause of some of the most significant cancer risks posed by toxic air pollution in the United States.<sup>15</sup> Ethylene oxide can also depress the central nervous system.<sup>16</sup> This can lead to seizures, loss of consciousness, nerve damage, or even coma; any of which may not even show up until six hours or more after the individual is exposed to the toxic gas.<sup>17</sup> Respiratory issues from EtO can range from irritation of the nose and throat, inflammation of airways and lining of the lungs, to even more serious problems such as lung collapse or respiratory paralysis.<sup>18</sup> Other health issues caused by this toxic gas include gastrointestinal issues, spontaneous abortions or miscarriages, and/or skin lesions that are at first painless and then develop into painful, itchy sores that may occur with direct exposure to the skin.<sup>19</sup>

According to EPA data, the number of Americans that face a cancer risk above the EPA guidelines because of being exposed to toxic air pollution are more than half a million.<sup>20</sup> A July 25, 2019, article in the Chicago Tribune, mentions that the EPA has found elevated cancer risks due to ethylene oxide exposure near companies that use or produce the gas in at least ten different states: Michigan, Louisiana, Texas, Georgia, Colorado, South Carolina, Missouri, Illinois, Pennsylvania, and New Mexico.<sup>21</sup> These companies range from industry giants like Dow Chemical and Shell, to smaller, lesser-known companies tucked away in the suburbs, such as Sterigenics and Medline Industries.<sup>22</sup> As a result of these companies being close to communities, in Louisiana, all three parishes (counties), face the risk of developing cancer from breathing toxic air pollution that the EPA finds unacceptable and that exceeds agency guidelines.<sup>23</sup> Further, according to the EPA report quietly released in August 2018, in Grand Rapids, Michigan, the state's second largest city, the residents of census tract had a lifetime risk of developing cancer nearly four

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12. *Id.*
  13. *Id.*
  14. *Id.* at 5.
  15. Hawthorne, *supra* note 2.
  16. ATSDR, *supra* note 9, at 5.
  17. *Id.*
  18. *Id.*
  19. *Id.* at 6-7.
  20. Hawthorne, *supra* note 2.
  21. *Id.*
  22. *Id.*
  23. *Id.*

times the national average.<sup>24</sup> Still, the EPA did not inform area residents or investigate the facility from which the gas was being emitted.<sup>25</sup> In the next section, which explains how ethylene oxide is regulated and the framework of federal, state, and local regulations, this Article will also address the lack of regulations and enforcement.

### III. ETHYLENE OXIDE REGULATION AND LACK OF ENFORCEMENT

This section will address various federal and state regulatory mechanisms related to ethylene oxide, as well as the framework for state and local government environmental action. First, it will review the Clean Air Act and the creation of the Environmental Protection Agency. Then, it will address the National Air Toxic Assessment, a screening tool used by the EPA for air pollution.<sup>26</sup> Next, it will discuss the framework of state and local environmental action. Finally, it will address the lack of enforcement throughout the years.

#### A. THE CLEAN AIR ACT AND THE ENVIRONMENTAL PROTECTION AGENCY

Regulation of hazardous pollutants that are released into the air, such as ethylene oxide, must follow the guidelines of the Clean Air Act (CAA).<sup>27</sup> The original Clean Air Act was passed in 1963 but only allocated funds for studying air pollution and for cleanup.<sup>28</sup> It was not until 1970 that Congress passed a version of the CAA that addressed air pollution and also created the Environmental Protection Agency.<sup>29</sup> At that time, it was the EPA's job to enforce the Clean Air Act, which "authorizes EPA to establish National Ambient Air Quality Standards (NAAQS) to protect public health and public welfare and to regulate emissions of hazardous air pollutants."<sup>30</sup> However, as part of these standards, "[b]etween 1970 and 1990, [the] EPA established regulations for only seven pollutants."<sup>31</sup> In 1990, Congress overhauled the CAA

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24. *Id.*

25. Hawthorne, *supra* note 2.

26. *NATA Overview*, U.S. ENV'T PROT. AGENCY (Aug. 27, 2018), <https://www.epa.gov/national-air-toxics-assessment/nata-overview> [<https://perma.cc/7H7T-YH7P>].

27. *Summary of the Clean Air Act*, U.S. ENV'T PROT. AGENCY (Aug. 15, 2019), <https://www.epa.gov/laws-regulations/summary-clean-air-act> [<https://perma.cc/KLM6-BW2U>].

28. *The Plain English Guide to the Clean Air Act*, U.S. ENV'T PROT. AGENCY 2 (Apr. 2007), <https://www.epa.gov/sites/production/files/2015-08/documents/peg.pdf> [<https://perma.cc/3RUC-HXU8>].

29. *Id.*

30. *Summary of the Clean Air Act*, *supra* note 26.

31. *The Plain English Guide to the Clean Air Act*, *supra* note 27, at 16.

giving the EPA the power to regulate and implement the reduction of air emissions from hazardous pollutants.<sup>32</sup> The EPA does this by limiting the amount of pollutants that can be in the air at a given time.<sup>33</sup> Additionally, the Amendments to the Clean Air Act in 1990, “required EPA to identify categories of industrial sources for 187 listed toxic air pollutants.”<sup>34</sup> Ethylene oxide was one of the toxic chemicals on the initial list of pollutants.<sup>35</sup> Section 112 of the CAA was also amended to establish technology-based standards for “stationary sources that emit or have the potential to emit 10 tons per year or more of a hazardous air pollutant or 25 tons per year or more of a combination of hazardous air pollutants.”<sup>36</sup> These are known as “major sources” of hazardous air pollutants.<sup>37</sup> Major sources require the EPA to “establish emission standards that require the maximum degree of reduction in emissions of hazardous air pollutants” or MACT standards.<sup>38</sup> MACT standards are known as maximum achievable control technology.<sup>39</sup> The EPA must review the MACT standards for a major source after eight years to determine if any risk exists and, if so, the EPA must revise the standards for that source in order to reduce the risk.<sup>40</sup> Any other stationary source that does not fall into that category is known as an area source and does not require MACT standards.<sup>41</sup> Although the 1990 update made significant changes, because the process is drawn out over many years and some sources still do not require monitoring, the problems with facilities emitting too much toxic emissions may go undetected and unremedied for many years.<sup>42</sup>

Although the Clean Air Act is a federal statute, individual state governments and branches of the EPA also play a vital role in the regulation of toxic chemicals.<sup>43</sup> Some states enact laws that require even stricter regulations than the CAA requires; however, all must meet the CAA’s minimum guidelines or risk sanctions from the federal EPA, who can also take over enforcement where it finds states lacking.<sup>44</sup> State and local governments monitor air

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32. *Id.* at 2.

33. *Id.* at 3.

34. *Id.* at 16.

35. *Initial List of Hazardous Air Pollutants with Modifications*, U.S. ENVTL. PROT. AGENCY (Mar. 16, 2017), <https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications> [<https://perma.cc/75RD-T8AW>].

36. *Summary of the Clean Air Act*, *supra* note 26.

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. *Summary of the Clean Air Act*, *supra* note 26.

42. *See* Fornek, *supra* note 3 (although Sterigenics facility was emitting ethylene oxide, there was no historical air sampling tests to compare it to because they had never been done).

43. *The Plain English Guide to the Clean Air Act*, *supra* note 27, at 2-3.

44. *Id.* at 3.

quality, inspect facilities, and enforce the CAA as well as issue permits.<sup>45</sup> Each state is required to develop a State Implementation Plan (SIPs) that explains how they will use the Clean Air Act to control air pollution and include which regulations, programs, and policies they will use to do so.<sup>46</sup> In creating the SIPs, states must hold public hearings and give the public, as well as the industries involved, a chance to comment on the proposed SIP.<sup>47</sup> Because state and local governments better understand the local industries, it is often better for the solutions to any air pollution problems to originate at this level as opposed to the federal level.<sup>48</sup> After the CAA amendments of 1990, states were required to implement a permit program for companies that release toxic pollutants into the air.<sup>49</sup> The permit must include what type of pollutant is being released, the amount the company is allowed to release, and steps that the company owner must take in order to reduce the pollution. Additionally, these “[p]ermits must include plans to measure and report the air pollution emitted.”<sup>50</sup> Before the Clean Air Act’s 1990 amendments, it was difficult for the EPA to enforce violations because even a minor violation required that the EPA take the violator to court. Since the 1990 amendments, however, the EPA can take a variety of actions including: issuing an order for the company to comply, giving the violator an administrative penalty, or bringing a civil action against them in court.<sup>51</sup> Additionally, a variety of screening tools have been put into place to help better understand air pollutants.

#### B. THE NATIONAL AIR TOXICS ASSESSMENT

In order to better understand what is required in the regulation of hazardous pollutants, the EPA created a screening tool.<sup>52</sup> The National Air Toxics Assessment (NATA) is a screening tool used by the EPA to help state and local agencies decide if they would like to conduct studies at certain places in order to understand what air pollutants and emissions sources pose a possible risk to the health of the public.<sup>53</sup> These air pollutants and emissions are known as air toxics. The NATAs are used by the EPA to, among other things, identify pollutants and source types of greatest concern.<sup>54</sup> They give an overview of air toxics emissions and possible long-term risks that could develop if the toxic emissions remain the same over many years.<sup>55</sup> The NATA

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45. *Id.*

46. *Id.*

47. *Id.*

48. *The Plain English Guide to the Clean Air Act*, *supra* note 27, at 3.

49. *Id.* at 19.

50. *Id.*

51. *Id.*

52. *NATA Overview*, *supra* note 25.

53. *Id.*

54. *Id.*

55. *Id.*



analyzes both cancer and noncancer risks caused by inhalation of the toxics over time when you breathe.<sup>56</sup> In order to do this, the NATA uses a four-step process: compiling national emissions inventory of outdoor air toxics sources, estimating ambient concentrations of air toxics across the U.S., estimating the population exposures, and determining potential public health risks from breathing the toxics.<sup>57</sup> NATAs have been conducted in 1996, 1999, 2002, 2011, and 2014.<sup>58</sup> However, the results of those tests are not released until four years after the test is conducted.<sup>59</sup> Given this, the most recent assessment was conducted in 2014 with the results released in 2018.<sup>60</sup>

### C. FRAMEWORK OF STATE AND LOCAL ENVIRONMENTAL ACTIONS

Although many environmental regulations are developed at the federal level, state and local level governments also have the ability to regulate some environmental issues, as discussed in the early section regarding the Clean Air Act. In addition to developing SIPs and issuing permits in accordance with the Clean Air Act, states also must follow the requirements of the Clean Water Act.<sup>61</sup>

The Clean Water Act (CWA) was designed in order to prevent and control water pollution.<sup>62</sup> Although state and local governments have authority over water in their state, federal agencies are required to work with them to establish programs to eliminate, reduce, and control water pollution.<sup>63</sup> In an attempt to do so, the CWA has made it against the law to empty pollutants into navigable waters through any point source without a permit to do so.<sup>64</sup> Navigable waters are waters that have been previously, or are now, used for interstate and/or foreign commerce, as well as those that ebb and flow with the tide.<sup>65</sup> Point sources are man-made ditches or conveyances, such as pipes.<sup>66</sup> Just like with the CAA permits, it is the state's job to issue permits to companies wishing to discharge pollutants into the water and to regulate their compliance.<sup>67</sup> These permits allow a business to discharge a certain

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56. *Id.*

57. *NATA Overview*, *supra* note 25.

58. *Id.*

59. *Id.*

60. *NATA Overview*, *supra* note 25.

61. 33 U.S.C.S. §1251 (LexisNexis); *Summary of the Clean Water Act*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/laws-regulations/summary-clean-water-act> [<https://perma.cc/2KJV-JFZ7>].

62. 33 U.S.C.S. §1521 (LexisNexis).

63. 33 U.S.C.S. §1521 (g) (LexisNexis).

64. *Summary of the Clean Water Act*, *supra* note 60.

65. 33 C.F.R. §329.4 (2021).

66. *Summary of the Clean Water Act*, *supra* note 60.

67. *Clean Water Act (CWA) Compliance Monitoring*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/compliance/clean-water-act-cwa-compliance-monitoring> [<https://perma.cc/4UQY-SDKL>].

amount of a chemical into water supplies.<sup>68</sup> In early 2000, the EPA promulgated new rules that required the states to report how much of each toxic chemical a water source could absorb and required the state to identify which businesses needed to reduce their pollutants accordingly.<sup>69</sup> Additionally, once these permits are issued, states are required to examine any new development plan by waterways to make sure that the level of pollutants has not increased.<sup>70</sup>

State and local governments can also decide how land in their communities is used through land use law.<sup>71</sup> According to an article written by the Environmental Law Institute regarding Land Use, regulating the use of land and the activities that can be conducted on it can have “a significant impact on human health and the environment.”<sup>72</sup> Most states have delegated the authority for how land is used to local municipalities through home rule or zoning provisions.<sup>73</sup> This allows local governments to determine how they want to plan out their cities and towns.<sup>74</sup> This also allows them to develop plans for their communities so that factories that emit toxic fumes are placed in areas far away from schools and heavily populated areas. However, there is a way to avoid land use and zoning laws called a variance.<sup>75</sup> Variances allow a business to locate in an area other than those that were originally planned.<sup>76</sup> Variances are granted when the municipality wants or needs the money or jobs that the company brings. Thus, municipalities may grant the company a variance and sacrifice their city plan in order to allow a business to locate where the company wants and not where it is most beneficial to the local community. When a municipality has no zoning laws or allows multiple variances, industrial plants that release toxic emissions can even be located in areas nearby where children attend school, or near other residential areas.<sup>77</sup> This is why it is important for local governments to set up land use provisions and only grant variances to them when they have thoroughly researched the company and the risks that it may pose to the public.<sup>78</sup>

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68. *Clean Water Act*, INC., <https://www.inc.com/encyclopedia/clean-water-act.html> [<https://perma.cc/B7CU-XBPS>].

69. *Id.*

70. *Id.*

71. *Land Use*, ENVTL. L. INST., <https://www.eli.org/keywords/land-use> [<https://perma.cc/C2SP-DTQ2>].

72. *Id.*

73. *Id.*

74. *Id.*

75. *See generally Land Use*, *supra* note 70.

76. *Id.*

77. Michael Hawthorne, *Will Plant Connected to Rauner Be Closed?; Neighbors Urge Strong Response to Polluting Site in Willowbrook*, CHI. TRIB. Sept. 23, 2018, at 4 (where the medical sterilization facilities are located within a mile of a day care center and four schools).

78. *See generally Land Use*, *supra* note 70.

Although the EPA has had the power to regulate and implement the reduction of air emissions from hazardous pollutants since the 1990s, the EPA's ability to monitor toxic air pollutants, such as ethylene oxide, is fairly recent considering the medical sterilization process using EtO was invented almost sixty plus years earlier in the 1930s.<sup>79</sup> This delay in the ability to monitor begs the question of what more will be learned about the hazards of this toxic chemical in the future and how much will be sacrificed until then. This begs the question whether the EPA's review of the residual risks of the MACT standards every eight years and the NATA's every four years is really enough. If not, the agency should change its standards to provide the public with the protection and the information that it needs about where it lives and works.

#### D. LACK OF ENFORCEMENT RELATED TO ETHYLENE OXIDE EMISSIONS

The effect of EtO versus the benefit of using the chemical for sterilization of medical equipment is multifaceted and, as is the case with most problems, often caught after much of the damage has been done. Many of the medical sterilization facilities are releasing this toxic gas into communities because regulations and laws have not come soon enough.<sup>80</sup> Further, the agencies that regulate them are often lax in enforcing the laws that are put into place.<sup>81</sup> In fact, the inaction of the EPA has been a reported pattern throughout the nation over the last several years.<sup>82</sup> Because of the EPA's lack of action, state environmental agencies are left to decide how to deal with the problem and they do not always do so.<sup>83</sup> Finally, despite requirements that they do so, businesses do not always self-report when they violate regulations or laws, and sometimes politicians with financial stakes in such companies appoint the heads of agencies where inspections and enforcement just happen to fail to occur with regularity.<sup>84</sup> Unfortunately, the lack of and delay in enforcement inevitably leads to a crisis. The next section will give you an example of how these crises can occur.

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79. STERIGENICS, *supra* note 4.

80. Hawthorne, *supra* note 2.

81. Hawthorne, *supra* note 76.

82. Hawthorne, *supra* note 2.

83. *Id.*

84. *See generally* Hawthorne, *supra* note 76. Illinois' former governor, Bruce Rauner, had investments in Sterigenics, after being elected governor he appointed the head of the Illinois EPA. *Id.*

#### IV. WHAT HAPPENED IN ILLINOIS-STERIGENICS

This section will demonstrate what happens when regulation and enforcement mechanisms fail by discussing a recent environmental health crisis in Illinois.<sup>85</sup>

Due to lack of regulation in the early years before the Environmental Protection Agency was formed or regulated hazardous chemicals, lack of enforcement once regulation was enacted, and the fact that the results of the requisite studies take years to be analyzed and released, environmental problems are often not recognized or resolved until a crisis occurs.<sup>86</sup> This section will address how one such crisis took place recently, in 2018, in a suburb of Chicago, Illinois.<sup>87</sup>

Sterigenics U.S., LLC, (Sterigenics) is a commercial medical sterilization company with its headquarters in Broadview Heights, Ohio.<sup>88</sup> Its parent company, f/n/a Sterigenics International, LLC, recently changed its name to Sotera Health,<sup>89</sup> more than likely as a result of the negative media attention related to the events of 2018. Sterigenics began its operations in the Chicago suburb of Willowbrook, Illinois, in 1984.<sup>90</sup> In a Chicago Tribune article, journalist Michael Hawthorne described the company's two industrial buildings as positioned behind a Target store and noted they "are about as nondescript as they come."<sup>91</sup> Sterigenics, "on a typical day, sterilizes approximately 1,000 medical devices used in heart surgery, 1,000 knee implants, 1,500 surgical kits, 16,000 catheters, 11,000 syringes, thousands of diabetes monitoring and care kits, and many other medical products."<sup>92</sup> Its mode of sterilization is ethylene oxide.<sup>93</sup>

In December of 2016, as the result of an Integrated Risk Information (IRIS) Assessment, it upgraded ethylene oxide from a probable carcinogen to a carcinogen.<sup>94</sup> In fact, due to the IRIS Assessment, the adult-based cancer risk of breathing in ethylene oxide was increased by thirty times what it had

85. Although this environmental health crisis occurred in Illinois, similar incidences are happening near sterilization facilities throughout the nation. *See generally* Hawthorne, *supra* note 2.

86. *See generally* NATA Overview, *supra* note 25.

87. Hawthorne, *supra* note 2.

88. Sterigenics U.S., LLC v. Kim, 385 F. Supp. 3d 600, 603 (N.D. Ill. 2019).

89. STERIGENICS, *supra* note 4.

90. Sterigenics, 385 F. Supp. 3d at 603.

91. Michael Hawthorne, *High Cancer Risk in Southeast DuPage County Linked to Company Co-owned by Rauner's Former Firm*, CHI. TRIB. (Aug. 28, 2018), <https://www.chicagotribune.com/news/breaking/ct-met-dupage-cancer-pollution-rauner-20180827-story.html> [<https://perma.cc/2VWT-9QAC>].

92. Sterigenics, 385 F. Supp. 3d at 603.

93. Hawthorne, *supra* note 76.

94. *Summary of Events Update*, VILL. WILLOWBROOK (Sept. 14, 2018), <https://www.willowbrookil.org/DocumentCenter/View/1423/Sterigenics-Summary-of-Events--Update-Sep-14?bidId=> [<https://perma.cc/4JVH-WR2L>].

been initially.<sup>95</sup> Following this assessment, the EPA decided to do some ambient air sampling around a known EtO emission source.<sup>96</sup> It looked to the NATA results in order to determine where to conduct additional studies.<sup>97</sup> Because of the NATA results, the EPA began to address the ethylene oxide emissions at Sterigenics in Willowbrook, Illinois.<sup>98</sup> Based on the most recent NATA, the EPA found seven census tracts, or areas with a population of 1,200-8,000 people in a city area of less than two square miles but bigger if in a rural area, around the Village of Willowbrook that were included in a nationwide group whose cancer risks exceeded a score of 100.<sup>99</sup> This means that out of one million people in the area, if continually exposed to ethylene oxide over their lifetime, one hundred of them would develop cancer due to that exposure. This increased rate of cancer is in addition to the normal cancer rates of a population that has not been exposed to EtO.<sup>100</sup>

The USEPA gathered air quality samples in May of 2018 from twenty-six areas around Sterigenics' Willowbrook facility.<sup>101</sup> The air samples, gathered over a three-day period, were tested to determine if ethylene oxide was present in the outdoor air and if so at what levels.<sup>102</sup> The agency used a short-term canister method for the sampling and stated that, “[w]hile this method was capable of measuring ethylene oxide at the concentrations observed during the short-term sampling period, this technique is not sensitive enough to measure levels of ethylene oxide at all levels that may present a long-term public health risk.”<sup>103</sup> This means that the EPA did not have the ability to measure ethylene oxide concentrations over a long term period.

Upon obtaining the results the EPA shared them with Sterigenics in June 2018.<sup>104</sup> Because the results showed high levels of emissions, Sterigenics asked the IEPA to issue them an additional permit in an attempt to rectify the matter by installing new emission controls. Even though the EPA's air testing

95. U.S. DEP'T OF HEALTH & HUM. SERVS, *Letter Health Consultation, Evaluation of Potential Health Impacts from Ethylene Oxide Emissions*, ATSDR (Aug. 21, 2018), [https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics\\_International\\_Inc-508.pdf](https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc-508.pdf) [<https://perma.cc/C5FY-PETL>].

96. *Id.*

97. *Sterigenics Willowbrook Facility - Background Information*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/il/sterigenics-willowbrook-facility-background-information#epa-involved> [<https://perma.cc/GED8-KAG6>].

98. *Id.*

99. Hawthorne, *supra* note 76; *Nat'l Air Toxics Assessment NATA Glossary of Terms*, U.S. ENV'T PROT. AGENCY, <https://www.epa.gov/national-air-toxics-assessment/nata-glossary-terms> [<https://perma.cc/7YYX-CPAQ>].

100. *Id.*

101. Fornek, *supra* note 3.

102. *Sterigenics Willowbrook Facility: What We Know*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/il/sterigenics-willowbrook-facility-what-we-know> [<https://perma.cc/N986-36FC>].

103. *Id.*

104. *Summary of Events Update*, *supra* note 93.

results clearly showed that Sterigenics emissions were violating their current permit, no action was taken against the facility and the IEPA still issued them a new permit to allow them to install new controls.<sup>105</sup> The new emission controls, installed in July of 2018, were supposed to reduce the emissions at the facility by 90 percent.<sup>106</sup> But additional testing would show that EtO emissions from the facility continued to be high.<sup>107</sup>

After the EPA began looking into Sterigenics, measuring the local ethylene oxide levels nearby, a related federal agency determined that the cancer risks in the area were even higher with six out of every 1,000 people at a risk of developing cancer from the exposure of the toxic chemical in the air.<sup>108</sup> A report released by the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry (ATSDR Report) found that Sterigenics was releasing levels of ethylene oxide into the air that could be harmful to the community.<sup>109</sup> After reviewing the EPA's May 2018 air quality samples from twenty-six areas around Sterigenics, the ATSDR Report showed "[t]hese elevated risks present a public health hazard to these populations."<sup>110</sup> However, the report also noted that, "[i]t [was] difficult to assess long-term public health implications from facility emissions because there [had] been no historical air monitoring in the community."<sup>111</sup> Even though Sterigenics had been in operation since 1984, and its predecessors since the early 1930s, and had been emitting toxic ethylene oxide into the air for likely much of that time, there had been no monitoring prior to the 2018 EPA investigation. This was so, despite the fact that a daycare and four other schools are all less than one mile away from the facilities.<sup>112</sup> It is unclear why the EPA took forty-eight years to finally test the air in this community, when it was quite aware, through the permit process, that the facilities were releasing this toxic gas into residential communities. That is especially troubling given that people in the community were developing, suffering, and even dying from cancer and respiratory problems, without knowing what was causing their health issues.<sup>113</sup>

While the 2018 tests were happening, and the United States EPA, Illinois EPA, Agency for Toxic Substances and Diseases Registry (ATSDR),

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105. *Id.*

106. *Id.*

107. *Id.*

108. Michael Hawthorne, *In About-Face, Gov. Bruce Rauner Calls for Sterigenics Shutdown After Weeks of Downplaying Cancer Risks*, CHI. TRIB. (Oct. 3, 2018), <https://www.chicagotribune.com/news/breaking/ct-met-bruce-rauner-sterigenics-shutdown-20181002-story.html> [<https://perma.cc/64JN-67BU>].

109. Fornek, *supra* note 3.

110. *Id.*

111. *Id.*

112. Hawthorne, *supra* note 90.

113. Vill. Willowbrook, *EPA Forum 8 29 2018*, YOUTUBE (Aug. 30, 2018), <https://youtu.be/swv3R2NpPXo> [<https://perma.cc/C8W8-2DTX>].

and Sterigenics were aware of the toxic emissions and the effect on the public, none of them would notify the Village of Willowbrook officials about the increased EtO emissions and the threat to the public's health until August 22, 2018, the very day that both the EPA's NATA and the ATSDR Report would be released.<sup>114</sup> Both reports were released to the public by the corresponding agencies on their websites and without notice.<sup>115</sup>

Two days following the reports' release, the mayor of Willowbrook posted a letter on the Village's website warning the public of the possible health hazards due to the levels of EtO in the air along with the ATSDR Report.<sup>116</sup> However, many residents did not check this website and instead learned about the EPA results from the local news. The following week, a public forum with the representatives from USEPA, IEPA, ATSDR, Sterigenics, and local elected officials was held by the Village to inform residents of the problem and allow them to voice their concerns.<sup>117</sup> Sandra Engberg, a long time Willowbrook resident interviewed for this Article, attended the forum.<sup>118</sup> Ms. Engberg reported that the agencies evaded questions regarding why the Village and residents were not informed of the newly determined toxicity of EtO and the increased emissions as soon as the EPA knew of the problem.<sup>119</sup> One by one, residents stood up, telling their stories of illnesses similar to those caused by EtO emissions.<sup>120</sup> One resident said his wife died of lymphoma, after suffering an extended illness, and asked if this was the cause.<sup>121</sup> Another man stood up with his eight-year-old daughter who was fighting leukemia.<sup>122</sup> Many more residents were angry and demanding answers, including Sandy, who after living less than a mile from Sterigenics since the early 1990s, now has so much lung damage that doctors told her that her lungs are that of a 95-year-old person despite being in her early sixties.<sup>123</sup> Infuriated by the lack of information and answers from the government agencies involved at the public forum, the Village of Willowbrook formed its own task force.<sup>124</sup> The task force hoped to gain more information from the ATSDR Report and keep the public informed while having more testing performed, including long-term monitoring.<sup>125</sup> Additionally, the Village went on to obtain the services of an environmental law firm, a toxicology

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114. *Summary of Events Update*, *supra* note 93.

115. *Id.*; Hawthorne, *supra* note 90.

116. *Summary of Events Update*, *supra* note 93.

117. *Id.*; *see also* VILL. WILLOWBROOK, *supra* note 112.

118. Telephone Interview with Sandra Engberg, Vill. of Willowbrook Resident (Aug. 30, 2018). Ms. Engberg is a friend of the author.

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.*

123. Telephone Interview with Sandra Engberg, *supra* note 117.

124. *Id.*

125. *Id.*

consulting firm, a chemical engineer, and a certified industrial hygienist in an attempt to find the answers itself.<sup>126</sup> The Mayor and Village officials then met with the Illinois Department of Public Health (IDPH) about performing a study regarding the incidence of cancer in the area.<sup>127</sup> These types of studies normally take eight to ten months to complete, but IDPH agreed to prioritize the study so that it would be completed in approximately six months.<sup>128</sup> Next, the Village reviewed its own codes, such as zoning ordinances, to see if the facility was in compliance with all the local laws and to determine what could be done, if anything, about areas in which the company was not in compliance.<sup>129</sup> For instance, at the first public forum, it was revealed that the Sterigenics facilities were actually zoned as light industrial, which did not permit facilities that emitted gas, odors, etc.<sup>130</sup> However, on September 3, 2018, the Village posted a historical review of the zoning for the properties, which stated that Sterigenics was in compliance with the 1975 Village Ordinances that were then grandfathered into the Village Zoning Ordinances in 1997.<sup>131</sup> Meanwhile, the Village had to wait for the facilities to finish installing their emission controls and conduct additional air testing to make sure those controls worked properly, which was scheduled by the EPA to occur in mid-September.<sup>132</sup>

On September 17, 2018, the Illinois Attorney General's Office reached out to the USEPA regarding the Letter Health Consultation prepared by ATSDR which stated the "alarmingly inadequate" ethylene oxide emission control at the Sterigenics facilities.<sup>133</sup> It asked the USEPA to work with Sterigenics to provide long-term ambient air monitoring and to work with ATSDR to provide the public with information by posting pertinent facts and relevant information on its website.<sup>134</sup> Although the additional air testing on the emission controls was carried out on September 20 and 21, 2018, the USEPA told Village officials, at a meeting in its offices, that it still would need to analyze those results and a final report could still be a month away.<sup>135</sup>

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126. *Summary of Events Update*, *supra* note 93.

127. *Id.*

128. *Id.*

129. *Id.*

130. *Summary of Events Update*, *supra* note 93.

131. *Zoning Review & Analysis of Sterigenics International, Inc.*, VILL. WILLOWBROOK, <https://www.willowbrookil.org/DocumentCenter/View/1399/Sterigenics-Zoning-Analysis-Draft-9518?bidId=> [<https://perma.cc/HWY8-SKAG>].

132. *Id.*

133. *Letters from the Illinois Attorney General*, VILL. WILLOWBROOK, <https://www.willowbrookil.org/DocumentCenter/View/1426/Letter-from-the-Illinois-AG?bidId> [<https://perma.cc/BCB8-D7AJ>].

134. *Id.*

135. Press Release, Vill. of Willowbrook Stack Testing, Mayor Trilla Attends Briefing Meeting at the USEPA (Oct. 1, 2018), <https://www.willowbrookil.org/DocumentCenter/View/1448/Willowbrook-Press-Release-on-Stack-Testing?bidId=> [[perma.cc/D37N-7APA](https://perma.cc/D37N-7APA)].



EPA officials were asked again if they could close the facilities while the report was pending. However, Village officials were told that the EPA was examining Section 112 of the CAA to determine if it had the authority to do so.<sup>136</sup> A few days later, on October 1, 2018, the Illinois EPA referred Sterigenics to the Illinois Attorney General's Office for an enforcement action.<sup>137</sup> It based its referral on the ATSDR Letter Health Consultation as well as information about the toxicity of the air quality that it was provided by the USEPA.<sup>138</sup> Additionally, the Illinois EPA pointed out that it would be weeks to months before the USEPA would be in a position to update the risk assessment; and in the interim, there was an increased concern because although the ATSDR Report had said the cancer risk had increased thirty times the previous known rate, the USEPA said it was actually a sixty-fold increase.<sup>139</sup> For these reasons, the IEPA requested the Attorney General to get an Order prohibiting Sterigenics from operating or to allege that Sterigenics violated Section 9(a) of the Illinois Environmental Protection Act, which provides:

No person shall:

(a) Cause or threaten or allow the discharge or emission of any contaminant into the environment in any State so as to cause or tend to cause air pollution in Illinois, either alone or in combination with contaminants from other sources, or so as to violate regulations or standards adopted by the Board under this Act.<sup>140</sup>

On October 30, 2018, the Illinois Attorney General, along with the DuPage County, Illinois State's Attorney filed a Complaint against Sterigenics U.S., LLC, for injunctive relief and civil penalties.<sup>141</sup> This two-count Complaint alleged that Sterigenics was causing, threatening, and allowing air pollution in violation of the Illinois Environmental Protection Act, and had done so from at least 2006 to July of 2018, by emitting 100% ethylene oxide pollution into the environment via their facilities' back vent valves.<sup>142</sup> Although Sterigenics had a permit from the IEPA to release emissions of EtO into the

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136. *Id.*

137. Press Release, Vill. of Willowbrook, Illinois EPA Refers Sterigenics to Att'y Gen. for Enf't (Oct. 2, 2018), <https://www.willowbrookil.org/DocumentCenter/View/1450/Sec-43a-Sterigenics-to-AG---Final?bidId=> [perma.cc/2DHW-GMPT].

138. *Id.*

139. *Id.*

140. *Id.*; 415 ILL. COMP. STAT. ANN. 5/9(a) (LexisNexis 2019).

141. Complaint, Illinois v. Sterigenics, 2018 WL 10398327 (Ill. Cir. Ct.) [hereinafter Complaint].

142. *Id.* at 1, 3-6.

air, the permit required that the facilities control 99% of EtO emissions from vacuum pump chamber evacuation systems and aeration rooms.<sup>143</sup> However, the permit did not require EtO emissions from back vent valves to be controlled.<sup>144</sup> Therefore, from the time the facilities began operations until July 2018, when Sterigenics installed the equipment allowing them to control these emissions, Sterigenics was violating the Illinois Environmental Protection Act.<sup>145</sup> The State's second count alleged that the facilities were a public nuisance in violation of the Illinois Constitution.<sup>146</sup> While the case made its way through the court system, the Village of Willowbrook continued to perform its own thirty day air quality tests that showed not only were the EtO emissions higher than they ever had been but also fluctuated daily.<sup>147</sup> Because of these testing results, the Illinois EPA issued a Seal Order and the facility was shut down.<sup>148</sup> A Seal Order is an order which allows the EPA to seal off certain parts of buildings related to pollution until the problem is rectified.<sup>149</sup> However, in July 2019, the Illinois Attorney General's Office, DuPage County State's Attorney, Illinois EPA, and Sterigenics entered into an Agreed Consent Order allowing the facility to resume operations under certain conditions.<sup>150</sup> But by this time, new legislation had been passed in Illinois regarding ethylene oxide emissions with even more new bills waiting to be passed.<sup>151</sup> The new legislation created much more stringent regulations on

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143. *Id.* at 4.

144. *Id.*

145. Michael Hawthorne, *Citing Cancer Risks, Lisa Madigan, DuPage Prosecutor Urge Court to Shut Down Sterigenics in Willowbrook*, CHI. TRIB. (Oct. 30, 2018), <https://www.chicagotribune.com/news/breaking/ct-met-lisa-madigan-dupage-sterigenics-lawsuit-20181029-story.html>; See Press Release, Kwane Raoul, Attorney General Raoul Urges EPA to Implement Stricter Ethylene Oxide Emission Standards and Find Alternatives to Ethylene Oxide Sterilization, ILL. ATTY. GEN. (Oct. 10, 2019), [http://illinoisattorneygeneral.gov/pressroom/2019\\_10/20191010.html](http://illinoisattorneygeneral.gov/pressroom/2019_10/20191010.html) [<https://perma.cc/FTP4-LGYR>].

146. Hawthorne, *supra* note 144.

147. Press Release, *New Air Sampling Results Calls For Emergency Action*, VILL. WILLOWBROOK (Feb. 15, 2019), <https://www.willowbrookil.org/DocumentCenter/View/1541/EtO-Follow-up-Testing-Results-Release-2-15-19-Final-plus-results?bidId=> [<https://perma.cc/YXW9-K9MN>].

148. Seal Order, Env'tl. Prot. Agency, Respondent Sterigenics U.S., LLC., SO: 2019- (Feb. 15, 2019) [https://www.willowbrookil.org/DocumentCenter/View/1542/Sterigenics\\_02152019164622?bidId=](https://www.willowbrookil.org/DocumentCenter/View/1542/Sterigenics_02152019164622?bidId=) [<https://perma.cc/XWU2-FB7G>].

149. *Id.* at 3.

150. Consent Order, People of the State of Ill. v. Sterigenics U.S., LLC, No. 2018 CH 001329 (Ill. Cir. Ct., July 17, 2019), <https://www.willowbrookil.org/DocumentCenter/View/1767/Sterigenics-Consent-Order-?bidId=> [<https://perma.cc/YD87-HB8C>].

151. *Illinois EPA information on Ethylene Oxide*, ILL. ENVTL. PROT. AGENCY (2020), <https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Pages/default.aspx> [<https://perma.cc/HK5L-D9LH>]; *Curran Sponsors New Bipartisan Ethylene Oxide Ban*, JOHN. F. CURRAN (Sep. 13, 2019), <http://senatorcurran.com/News/889/Curran-sponsors-new-bipartisan-ethylene-oxide-ban/news-detail/> [<https://perma.cc/7WP2-HEAM>].

the emissions of ethylene oxide.<sup>152</sup> On September 30, 2019, with the facility still closed, Sterigenics announced that because of Illinois's "unstable legislative and regulatory landscape" and a failed lease renewal, it had decided not to reopen the facilities.<sup>153</sup> Although personal litigation is ongoing in attempting to rectify past wrongs and health issues of those involved,<sup>154</sup> in order to prevent situations like this in the future, preventative legislation needs to be enacted and enforced. In the next section, this Article will discuss the various legal remedies to be considered.

## V. LEGAL REMEDIES FOR ENVIRONMENTAL POLLUTION

While there are existing frameworks in place through the federal and state environmental protection agencies, they fail to provide sufficient protection to the public, as demonstrated by the fact that the system breaks down again and again throughout the nation.<sup>155</sup> Because of this, it is imperative that states enact their own legislation to protect their citizens. This section of the Article will look specifically at the laws enacted in Illinois because of the crisis there. Next, it will look at the patchwork of remedies that have been put into place across the nation. Then moving on, it will discuss the consequences of rectifying the EtO problem. Finally, it will address the conflict between the EPA and FDA in regard to medical sterilization.

### A. ARE ILLINOIS'S NEW LAWS THE STRICTEST IN THE NATION?

Shortly after the Illinois Attorney General's lawsuit against Sterigenics was filed, in October of 2018, lawmakers went to work to try to find some type of legislation that would limit or ban the use of ethylene oxide in Illinois.<sup>156</sup> By May 2019, IL SB1852 and IL SB1854 were approved by both

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152. Matt Haller Act, Sen. Res. 1852, 101st Gen. Assemb., (Ill. 2019); Act of June 21, 2019, Pub. Act. 101-0022, 2019, Amends IL Envtl. Prot. Act. 415 ILCS 5/9.16.

153. David Lim, *Sterigenics Abandons Its Efforts to Reopen Willowbrook Ethylene Oxide Sterilization Facilities*, MEDTECH DIVE (Sept. 30 2019), [https://www.medtechdive.com/news/sterigenics-willowbrook-ethylene-oxide-sterilization/564042/\[https://perma.cc/TX7H-F8NJ\]](https://www.medtechdive.com/news/sterigenics-willowbrook-ethylene-oxide-sterilization/564042/[https://perma.cc/TX7H-F8NJ]).

154. Kimberly Fornek, *76 Lawsuits Have Been Filed Over Ethylene Oxide Emissions at Sterigenics Plant in Willowbrook and More May be Coming, Attorney Says*, CHI. TRIB. (Jan. 30, 2020), [https://www.chicagotribune.com/suburbs/burr-ridge/ct-dbr-sterigenics-willowbrook-lawsuits-tl-0206-20200130-2xf3dqihjjdfpenrokeami5pea-story.html \[https://perma.cc/L9CZ-2MZX\]](https://www.chicagotribune.com/suburbs/burr-ridge/ct-dbr-sterigenics-willowbrook-lawsuits-tl-0206-20200130-2xf3dqihjjdfpenrokeami5pea-story.html [https://perma.cc/L9CZ-2MZX]).

155. Hawthorne, *supra* note 2.

156. Mike Riopell, *Illinois Senate Narrowly Votes to Raise Age to Buy Cigarettes to 21, in One of Many Votes to Override Gov. Bruce Rauner*, CHI. TRIB. (Nov. 15, 2018), [https://www.chicagotribune.com/politics/ct-met-illinois-legislature-bruce-rauner-veto-20181114-story.html \[https://perma.cc/99BR-MJZ9\]](https://www.chicagotribune.com/politics/ct-met-illinois-legislature-bruce-rauner-veto-20181114-story.html [https://perma.cc/99BR-MJZ9]).

Houses and the Governor signed them into law on June 21, 2019.<sup>157</sup> Both laws had immediate effective dates.<sup>158</sup>

Public Act 101-0022 is otherwise known as the Matt Haller Act.<sup>159</sup> Mr. Haller, who lived a mile from Sterigenics, had stomach cancer and filed a lawsuit against the company.<sup>160</sup> Shortly after, he was the first plaintiff to die, at the age of forty-five.<sup>161</sup> The Matt Haller Act requires that facilities capture 100% of all ethylene oxide emissions within their facility and reduce EtO emissions in the air from every exhaust area by 99.9%.<sup>162</sup> Additionally, within 180 days of this law being enacted, all facilities were required to conduct an initial emissions test, which must be repeated yearly.<sup>163</sup> If a facility fails the emissions test, it must stop operations, notify the Illinois EPA within twenty-four hours, and then has sixty days to figure out why it failed the test and correct the problem.<sup>164</sup> Once the issue is rectified, IEPA must give its approval before the facility can again begin operations.<sup>165</sup> Additionally, facilities that use EtO for sterilization purposes must conduct ambient air testing quarterly.<sup>166</sup> Further, IEPA construction permits must be sought before making any changes based on compliance with the emissions limits.<sup>167</sup> If a facility has been previously closed due to a Seal Order relating to EtO emissions, the facility must certify to the IEPA that EtO sterilization is the only available way to sterilize its product and that technology that it uses for the facilities emission control produces the highest possible reduction in EtO emissions available.<sup>168</sup> At the beginning of 2020, a provision of the law took effect requiring facilities that sterilize with EtO to be located at least ten miles from parks and schools.<sup>169</sup> This shows that lawmakers took into account how many children have been affected by the Willowbrook disaster because of the four schools within a mile of the facilities.

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157. Matt Haller Act, 415 ILL. COMP. STAT. ANN. 5/9.16 (LexisNexis 2020).

158. *Illinois EPA Information on Ethylene Oxide*, ILL. ENVTL. PROT. AGENCY (2020), <https://www2.illinois.gov/epa/topics/community-relations/sites/ethylene-oxide/Pages/default.aspx> [<https://perma.cc/HK5L-D9LH>].

159. *New Law Named After Matt Haller Puts Strict Limits on Toxic Ethylene Oxide Emissions; 'An Everlasting Legacy'*, CBS CHI. (June 24, 2019), <https://chicago.cbslocal.com/2019/06/24/matt-haller-act-ethylene-oxide-emissions-sterigenics-willowbrook/> [<https://perma.cc/89E4-Y4ZR>].

160. *Id.*

161. *Id.*

162. Matt Haller Act, 415 ILL. COMP. STAT. ANN. 5/9.16 (LexisNexis 2020).

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.*

167. Matt Haller Act, 415 ILL. COMP. STAT. ANN. 5/9.16 (LexisNexis 2020).

168. *Id.*

169. *Id.*

The second June 2019 law that was passed regarding EtO was Public Act 101-0023.<sup>170</sup> This Act covers facilities that do not use EtO for sterilization.<sup>171</sup> Under this law, no facility is allowed to emit ethylene oxide into the air unless it submits a plan to IEPA for review and approval to do so.<sup>172</sup> This plan must include dispersion modeling.<sup>173</sup> Dispersion modeling is a mathematical formula that explains the process that disperses a toxic pollutant into the atmosphere.<sup>174</sup> Within 180 days of this law going into effect, facilities had to submit their plans to the IEPA in order to obtain a permit.<sup>175</sup> The permit must also include an annual cap on the facility's EtO emissions at each particular site.<sup>176</sup> Further, this cap must be set at an emissions rate that protects public health.<sup>177</sup> The IEPA is allowed to reopen and review any permit at any time if the IEPA fears that the EtO emissions from the facility puts the public's health at risk.<sup>178</sup>

In addition to these legislative advances, two more bills addressing EtO are making their way through the Illinois General Assembly. HB3885 was introduced to the House in September 2019 and requested to amend the Environmental Protection Act to state that nothing in the Act will prohibit local Home Rule units of government from imposing their own additional restrictions on ethylene oxide emissions of sterilization facilities within their home rule jurisdictions and that are allowed to emit EtO.<sup>179</sup> In late October, this bill failed to pass out of the Energy and Environment Committee but was referred back to the Rules Committee in November where it currently resides.<sup>180</sup> HB3888, which was introduced at the same time, focuses on phasing out the use of ethylene oxide sterilization by 2021 in heavily populated areas and completely bans the use of EtO by hospitals in areas with large populations by 2022.<sup>181</sup> Although the bill was passed in the House in October 2019,<sup>182</sup> it has not fared as well in the Senate. The bill failed a committee

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170. 415 ILL. COMP. STAT. ANN. 5/9.16 (LexisNexis 2020).

171. *Id.*

172. *Id.*

173. *Id.*

174. *Air Quality Dispersion Modeling*, ENVTL. PROT. AGENCY, <https://www.epa.gov/scram/air-quality-dispersion-modeling> [https://perma.cc/HHH7-XMVV].

175. *Illinois EPA Information on Ethylene Oxide*, *supra* note 157.

176. *Id.*

177. 415 ILL. COMP. STAT. 5/9.16 (2020).

178. *Id.*

179. H.R. Res. 3885, 101st Gen. Assemb. (Ill. 2019).

180. *Id.*

181. *Curran Sponsors New Bipartisan Ethylene Oxide Ban*, *supra* note 150.

182. Michael Hawthorne, *Illinois House Approves Phaseout of Cancer-causing Ethylene Oxide, but Medline Industries and Business Groups Are Working To Quash Bill in Senate*, CHI. TRIB., (Oct. 30, 2019), <https://www.chicagotribune.com/news/environment/ct-ethylene-oxide-illinois-house-bill-20191030-zh4i7a5szbhlj1562q74skfapu-story.html> [https://perma.cc/7NDA-2HYH].

vote in November, underwent some amendments, and has since been referred to Assignments Committee once again.<sup>183</sup>

#### B. THE PATCHWORK OF DIVERSE REMEDIES THROUGHOUT THE NATION

Media and lawmakers have said that these new laws regarding restrictions on ethylene oxide are “the toughest in the nation.”<sup>184</sup> However, Illinois was a little late to the game adopting and proposing laws only after learning of the health crisis in 2018. In the late 1990s, there was a nationwide concern over the way companies handle EtO following a series of explosions.<sup>185</sup> During this time, the Bush Administration had been convinced to relax clean air standards and let facilities forgo some of the pollution-control equipment.<sup>186</sup> This reduction in required standards led many companies to vent the emissions directly into the air.<sup>187</sup> Because states are allowed to set restrictions that are even more strict than the federal government in regard to toxic chemicals, such as ethylene oxide, other states, such as California, adopted their own laws requiring filtering of the EtO emissions at that time.<sup>188</sup> However, Illinois did not do so and EtO emissions in Illinois continued to be dispersed into the air for the public to breathe.<sup>189</sup> This varied approach by states to emissions reduction shows that even though the federal government has established procedures in regard to toxic chemicals, state governments also need to be proactive to best protect their residents.

As previously mentioned, California is one state that more proactively legislates emissions.<sup>190</sup> As early as 1983, California created a program to reduce exposure to air toxics, called the Toxic Air Contaminant Identification and Control Act.<sup>191</sup> This program, which is still in effect today, requires that

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183. Jamie Munks, *Bill to Phase Out Cancer-causing Ethylene Oxide Fails in Illinois Senate Committee Vote; Lawmakers Push for More Talks Before Taking Up the Issue Again Next Year*, CHI. TRIB. (Nov. 13, 2019), <https://www.chicagotribune.com/ct-ethylene-oxide-committee-20191114-4eshm6wvzzchra7ygv3fokusda-story.html> [https://perma.cc/9QZP-NWBW]. There has been some controversy surrounding HB3888 which will be discussed more in the section regarding the Federal Food and Drug Administration.

184. Michael Hawthorne, *How Tough Is the Illinois Law on Ethylene Oxide? Not Nearly Tough Enough, Some Lawmakers and Residents Say*, CHI. TRIB., Oct. 16, 2019.

185. Michael Hawthorne, *New Documents Reveal How Sterigenics, Other Companies Were Allowed To Vent Cancer-Causing Gas Into Communities*, CHI. TRIB., (Nov. 29, 2018), <https://www.chicagotribune.com/news/environment/ct-ethylene-oxide-tougher-legislation-20191016-6gozif3mcfa2pd6qagdpo3me4-story.html> [https://perma.cc/U4RJ-GDPN].

186. *Id.*

187. *Id.*

188. *Id.*

189. *Id.*

190. Hawthorne, *supra* note 181.

191. CALIF. AIR RES. BD., *Ethylene Oxide Airborne Toxic Control Measure*, STATE CAL. (2020), <https://ww2.arb.ca.gov/ethylene-oxide-airborne-toxic-control-measure-atcm> [https://perma.cc/VMJ5-WD7R].

toxic substances be identified and the exposures to the substances be reduced to the lowest possible exposure when taking both risk of the public and cost to the company into account.<sup>192</sup> Staying on top of environmental concerns, California identified EtO as a toxic air contaminant as early as 1987.<sup>193</sup> To that end, by 1990, California had enacted a measure to reduce ethylene oxide emissions.<sup>194</sup> By being proactive, California residents were spared almost thirty years of breathing EtO emissions where Illinoisans were not.<sup>195</sup>

Georgia, a state that recently survived a crisis very similar to that in Illinois caused by a Sterigenics facility near Smyrna, has proposed new legislation as well.<sup>196</sup> On January 14, 2020, House Resolution 895 was introduced to create the Joint Ethylene Oxide Study Committee.<sup>197</sup> The Committee would consist of four members of the House, four members of the Senate, the Director of the Environmental Protection Division, and the Commission of Public Health.<sup>198</sup> The Committee would study EtO emissions between the time of formation and December 2020 in order to study the effects, issues, needs, and problems relating to EtO and the eight facilities in the State that use it.<sup>199</sup> Additionally, HB774, introduced the same day, was proposed to amend Title 12, Chapter 9, Article 1 of the Georgia Annotated Code.<sup>200</sup> The bill would require the reporting of any unpermitted release of EtO to the Environmental Protection Division, require the EPD to notify the public of this unpermitted release, repeal conflicting laws, and would address other environmental issues.<sup>201</sup> Although both HR895 and HB774 are in the beginning stages of legislation, State Representative Erick Allen told a newspaper back in November 2019, that he wanted to “introduce ‘a package of bills’ addressing the issuance of permits, testing, and monitoring related to ethylene oxide use in Georgia.”<sup>202</sup> He went on to say that proposed bills would not only require exactly what has been proposed in HB774, but also require EtO testing at the exhaust point, and mandate the Georgia EPA monitor emissions of the gas continuously at all locations where EtO is used commercially.<sup>203</sup> This

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192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*; Hawthorne, *supra* note 181.

196. Rosie Manins, *Laws to Curb Ethylene Oxide Emissions Proposed by Cobb Democrat*, MARIETTA DAILY J. (Nov. 8, 2019), [https://www.mdjonline.com/news/laws-to-curb-ethylene-oxide-emissions-proposed-by-cobb-democrat/article\\_664a4446-0240-11ea-9635-e7be7c5deedd.html](https://www.mdjonline.com/news/laws-to-curb-ethylene-oxide-emissions-proposed-by-cobb-democrat/article_664a4446-0240-11ea-9635-e7be7c5deedd.html) [<https://perma.cc/VMJ5-WD7R>].

197. Georgia Gen. Assemb., *2019-2020 Regular Session - HR 895 Joint Ethylene Oxide Study Committee*, [http://www.legis.ga.gov/Legislation/en-US/display/20192020/HR/895\\_](http://www.legis.ga.gov/Legislation/en-US/display/20192020/HR/895_)

198. *Id.*

199. *Id.*

200. *Id.*

201. H.B. 774, 155th Gen. Assemb., Reg. Sess. (Ga. 2020); <http://www.legis.ga.gov/Legislation/en-US/display/20192020/HB/774>.

202. Manins, *supra* note 195.

203. *Id.*

statement indicates that more bills may be added to those already proposed this year.<sup>204</sup>

However, not all states seem interested in addressing the USEPA's upgraded conclusion that ethylene oxide is sixty times more carcinogenic than thought in the past, or at least they seem to be fine with the status quo.<sup>205</sup> For instance, Indiana does not have its own standards for ethylene oxide sterilization, simply incorporating the federal standards as its own.<sup>206</sup> Additionally, the Texas Commission on Environmental Quality (TCEQ) decided in September 2019, that the USEPA overestimated the carcinogenic risk of the gas and proposed raising the long-term exposure threshold to 4 parts per billion instead of 1 part per billion.<sup>207</sup> TCEQ decided that the USEPA's science on the matter is flawed and unrealistic.<sup>208</sup> However, a former TCEQ air inspector believes that if the Texas measure is approved, it will result in more pollution and less protection of not only EtO but other carcinogenic chemicals as well.<sup>209</sup>

Since federal standards are less stringent, states are beginning to adopt individual laws to protect residents in their own state. The sterilization industry complains that this state-by-state approach leads to confusion for those in the device industry as to how to comply.<sup>210</sup> During a recent conference, one CEO expressed his concern this way, "Imagine if you had products in manufacturing facilities in 20 states with 20 different sets of regulations . . . [y]ou would have to outfit every facility differently and make different adjustments for every facility."<sup>211</sup> Industry leaders are hoping that the EPA will come up with a federal standard with which every state can comply.<sup>212</sup> But with the gamut of laws running from super strict, such as those in Illinois, to those fighting to even fulfill the bare minimum of the federal standard, like Texas hopes to pass, this uniform regulation does not seem likely to happen.

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204. *Id.*

205. Perla Trevizo, *Texas Regulators May Raise the Acceptable Level of a Toxic Chemical. Activists and East Harris County Residents Are Worried*, HOUS. CHRON. (Sept. 2, 2019), <https://www.houstonchronicle.com/news/houston-texas/houston/article/Texas-regulators-may-raise-the-acceptable-level-14403150.php> [<https://perma.cc/G7U4-ZXQF>].

206. 326 IND. ADMIN. CODE 20-5-1(c) (2019).

207. Trevizo, *supra* note 204.

208. *Id.*

209. *Id.*

210. Ayanna Alexander, *State-by-State Sterilizer Rules Worry Medical Device Makers*, BLOOMBERG (Sept. 23, 2019, 1:52 PM), <https://news.bloomberglaw.com/health-law-and-business/state-by-state-sterilizer-rules-worry-medical-device-makers> [<https://perma.cc/D7S7-R3RJ>].

211. *Id.*

212. *Id.*



## VI. THE CONSEQUENCES OF RECTIFYING ETHYLENE OXIDE EMISSIONS

Many people believe that all of the new legislation surrounding ethylene oxide is long overdue because of the risks to their health. However, if EtO is limited or banned in some states, there is a concern that this may cause a health crisis of another type, as the United States Food and Drug Administration (FDA) warns.<sup>213</sup>

As an example of this, Illinois House Bill 3888, which hopes to entirely phase out ethylene oxide use in the state, has faced much controversy.<sup>214</sup> On one side, residents who live and work near these facilities are developing cancer and other health issues at record rates, as concluded by the ATSDR Report.<sup>215</sup> On the other side, the FDA warns “that additional closures of facilities using ethylene oxide to sterilize medical devices could lead to equipment shortages that compromise patient care.”<sup>216</sup> Although the FDA understands the environmental concerns, the shutdown of sterilization facilities that use EtO for medical device sterilization has an impact on the medtech industry.<sup>217</sup> The FDA warns that the closures of ethylene oxide sterilization facilities will “threaten the lives of patients and limit their access to everything from pacemakers to equipment for hip replacements.”<sup>218</sup> In April 2019, while Sterigenics was closed, the FDA acknowledged a shortage of tracheostomy tubes used to help adults and children with high-risk illnesses breathe.<sup>219</sup> The shortage problem further snowballs when other facilities throughout the nation are being shut down for the same reasons.<sup>220</sup> In Michigan, another sterilization company, Viant Medical, closed its sterilization facility in Grand Rapids because the Michigan Department of Environmental Quality issued it a violation for air quality issues due to an EtO leak.<sup>221</sup> As a result of the shutdown of just these two facilities, the FDA urged the medical

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213. Norman E. Sharpless, *Statement on Concerns with Medical Device Availability Due to Certain Sterilization Facility Closures*, U.S. FOOD & DRUG ADMIN. (Oct. 25, 2019), <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures> [<https://perma.cc/5K25-C55S>].

214. *Id.*

215. U.S. DEP’T OF HEALTH & HUM. SERVS., *supra* note 94.

216. Munks, *supra* note 182.

217. Amanda Pedersen, *FDA Scrambles to Prevent Shortages Amid Sterilization Shutdowns*, MDDI (Mar. 26, 2019), <https://www.mddionline.com/fda-scrambles-prevent-shortages-wake-sterilization-shutdowns> [<https://perma.cc/7V7B-9ZXA>].

218. Sarah Karlin-Smith, Annie Snider & Sarah Oweremohle, *How the FDA and EPA’s Failure To Communicate Could Put Patients in Danger*, POLITICO (Nov. 7, 2019, 5:01 AM), <https://www.politico.com/news/2019/11/07/fda-epa-cancer-pollution-medical-devices-067141> [<https://perma.cc/B79K-42KM>].

219. Amanda Pedersen, *FDA Acknowledges Shortage of Breathing Tubes Due to Sterilization Shutdown*, MDDI (Apr. 15, 2019), <https://www.mddionline.com/fda-acknowledges-shortage-breathing-tubes-due-sterilization-shutdown> [<https://perma.cc/P9JY-LRV9>].

220. *Id.*

221. Pedersen, *supra* note 216.

community to take note of the impact of the closures on their supplies as well as patient care.<sup>222</sup> The FDA launched a new webpage dedicated to EtO sterilization to serve as a resource for ethylene oxide sterilization and provide information on actions the FDA could take regarding shortages of sterilized medical equipment.<sup>223</sup> The FDA is also trying to encourage innovation by issuing challenges for companies to find other ways to sterilize these products and/or reduce emissions of ethylene oxide at the sterilization sites.<sup>224</sup> The FDA received twenty-four applications in response to this challenge and has now chosen to further research five different methods proposed by four companies.<sup>225</sup> The FDA will work with these companies in an attempt to encourage innovative technology and develop new ways of sterilizing medical equipment.<sup>226</sup> Unfortunately, nobody knows how long the process will take or if they will be able to come up with an alternative that will work for all types of medical devices and equipment that does not involve a similarly toxic chemical.<sup>227</sup>

#### A. EPA VS. FDA, WHEN TWO FEDERAL AGENCIES CONFLICT

Although both the EPA and the FDA are working to rectify their individual problems with ethylene oxide, a November news article asks why the two government agencies have not been working together to find a solution.<sup>228</sup> Although the EPA realized in 2014 that there was a cancer risk linked to ethylene oxide, and thus medical sterilization facilities, it seems that the FDA was not made aware of the dire situation until 2018, when facilities began closing due to emission violations.<sup>229</sup> Since nobody connected the dots between the two agencies until a crisis occurred, approximately five years were lost during which the FDA could have been issuing innovation challenges and trying to find a solution.<sup>230</sup> In response to this criticism, the FDA said that because regulating air pollution is not in its jurisdiction, there was no way for it to know there would be a crisis.<sup>231</sup> At the very least, such a response shows that the agencies do not communicate adequately. Likewise, a medical device lobbyist said that “the 2016 conclusions from EPA’s

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222. *Id.*

223. *Id.*

224. *Id.*

225. *FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies> [<https://perma.cc/3ARE-AMWM>].

226. *Id.*

227. *Id.*

228. Karlin-Smith, Snider & Owerhohle, *supra* note 217.

229. *Id.*

230. *Id.*

231. *Id.*

Integrated Risk Information System program were never meant to create a new limit that policymakers would use to regulate pollution.”<sup>232</sup> This “pass the buck” attitude seems to be exactly the cause of the current crisis. Yet, at the time of this Article, the FDA is still looking for new science to create sterilization methods that do not use this toxic gas, and the EPA is addressing the battles of the toxic emission on a case-by-case basis.<sup>233</sup> There is still no evidence that the two agencies are working together to solve the problem. In fact, in December 2019, the EPA announced that, before it makes changes to its National Emissions Standard for Hazardous Pollutants, it was releasing advanced notice of proposed rulemaking to obtain public comments regarding what work processes and technologies are currently being used.<sup>234</sup> The EPA was also specifically going to ask companies whether they “could use lower volumes of ethylene oxide to sterilize medical equipment.”<sup>235</sup> However, during an interagency review the FDA claimed jurisdiction over the use of ethylene oxide in medical sterilization facilities.<sup>236</sup> On the EPA’s notice of proposed rulemaking, the FDA commented that “[t]he FDA believes this entire section is not relevant to EPA’s role of setting appropriate emissions levels and monitoring emissions . . . [the] FDA requests the deletion of this entire discussion about FDA requirements and matters within FDA jurisdiction.”<sup>237</sup> The FDA claimed that it was responsible for the safety of medical devices and how much sterilizer is used and that the EPA had no authority in that space.<sup>238</sup> The FDA went on to say that the only authority the EPA had was over the emissions of the chemicals being released into the air from the factories.<sup>239</sup> An FDA spokesperson further stated that “the FDA’s comments on the notice ‘point[s] out that setting emission[s] standards should not be about medical device sterilization.”<sup>240</sup> It should be about protecting the

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232. *Id.*

233. *FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies*, *supra* note 224.

234. Amena H. Saiyid, *EPA Touts Plugging Ethylene Oxide Leaks at Medical Sterilizers*, BLOOMBERG (Dec. 5, 2019, 4:43 PM), <https://news.bloomberglaw.com/environment-and-energy/epa-touts-plugging-ethylene-oxide-leaks-at-medical-sterilizers> [<https://perma.cc/LEX5-P9HA>].

235. Chuck McCutcheon, *FDA Prevails Over EPA in Jurisdictional Debate on Toxic Chemical*, BLOOMBERG (Jan. 17, 2020, 5:55 AM), <https://news.bloomberglaw.com/environment-and-energy/fda-prevails-over-epa-in-jurisdictional-debate-on-toxic-chemical-56> [<https://perma.cc/M2JD-5G28>].

236. *Id.*

237. Amena H. Saiyid & Ayanna Alexander, *EPA Dilutes Plan on Carcinogen Ethylene Oxide After FDA Push*, BLOOMBERG, (Jan. 17, 2020, 6:39 PM), <https://news.bloomberglaw.com/environment-and-energy/epa-waters-down-plan-on-carcinogen-ethylene-oxide-after-fda-push> [<https://perma.cc/B4ZQ-VT3D>].

238. *Id.*

239. *Id.*

240. *Id.*

environment and protecting the people.”<sup>241</sup> Although an EPA spokesperson told Bloomberg Environment that the EPA, under the Clean Air Act, is required to consider every emissions source within a facility, when setting pollution limits it conceded to the FDA comments and removed the entire section as requested.<sup>242</sup>

With all this interagency conflict, it is important to note that current sterilization procedures use “overkill,” which is a process of sterilizing the piece of equipment for longer than is actually required.<sup>243</sup> This is done so that the product will be sterile throughout its functional lifetime.<sup>244</sup> Because the FDA wants to limit the EPA’s ability to ask questions regarding processes used in medical device sterilization, it has taken away an avenue by which the EPA may have been able to limit toxic emissions.<sup>245</sup> With the two agencies still at odds over their differing agendas, it once again seems to fall back to state and local governments to decide what is best for their communities and advocate with the agencies accordingly.

## VII. CONCLUSION

Ethylene oxide is a toxic, carcinogenic gas used to sterilize over 50 percent of the medical devices in the United States today.<sup>246</sup> Throughout the country, the facilities that sterilize medical devices using this method release toxic emissions of EtO into the air.<sup>247</sup> The EPA has taken many years to catch up with science to determine the carcinogenic nature of these gases.<sup>248</sup> But recently, the EPA has found that by releasing these toxic emissions, residents surrounding the facilities are developing cancer and other ailments at alarming rates.<sup>249</sup> However, ethylene oxide is often the only sterilization process that can be used on a variety of devices made out of sensitive materials.<sup>250</sup> As the EPA, and individual states, attempt to crack down on the facilities that emit the ethylene oxide into the environment, the FDA warns that these measures are causing a shortage of sterilized medical devices needed for proper medical treatment.<sup>251</sup>

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241. *Id.*

242. Saiyid & Alexander, *supra* note 236.

243. *Id.*

244. *Id.*

245. *Id.*

246. Sharpless, *supra* note 1.

247. Hawthorne, *supra* note 2.

248. Press Release, Ill. Env'tl. Prot. Agency, Illinois EPA Refers Sterigenics to Attorney General for Enforcement, Vill. Willowbrook (Oct. 2, 2018), [https://www.willowbrookil.org/DocumentCenter/View/1450/Sec-43a-Sterigenics-to-AG---Final?bidId=\[https://perma.cc/2DHW-GMPT\]](https://www.willowbrookil.org/DocumentCenter/View/1450/Sec-43a-Sterigenics-to-AG---Final?bidId=[https://perma.cc/2DHW-GMPT]).

249. Hawthorne, *supra* note 2.

250. *Ethylene Oxide Sterilization of Medical Devices*, *supra* note 6.

251. Pedersen, *supra* note 218.

As seen in the regulation of EtO, when federal agencies do not communicate and/or conflict over the jurisdictions of each, solutions often come too late or not at all.<sup>252</sup> Additionally, solutions are not sought until a crisis occurs. When a crisis finally does occur, the public demands answers.<sup>253</sup> It seems that only then can the search for solutions really begin. Solutions can be found in a variety of legal actions that are taken at either the federal or state and local levels.<sup>254</sup>

States can enact new legislation in order to protect the residents of their states. Local governments and municipalities can use home rule and land use laws in order to develop and plan zoning in a way which will keep industries in their communities away from highly populated areas and schools. However, the patchwork of individualized solutions is making it difficult for the industry to keep up with the different regulations throughout the country.<sup>255</sup> It is imperative that the EPA and FDA work together with state and local governments to come up with solutions that will keep everyone, whether living near the medical sterilization facilities or in need of the sterilized medical devices, all safe from health concerns.

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252. Hawthorne, *supra* note 2.

253. *Id.*

254. *Id.*

255. Ayanna Alexander, *State-by-State Sterilizer Rules Worry Medical Device Makers*, BLOOMBERG (Sept. 23, 2019, 1:52 PM), <https://news.bloomberglaw.com/health-law-and-business/state-by-state-sterilizer-rules-worry-medical-device-makers?context=search&index=5> [<https://perma.cc/LDX4-2QE2>].