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## Public Health vs. Public Health: Balancing Environmental Concerns with the Need for Sterile Medical Devices

Jack Brooksbank

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## Public Health vs. Public Health: Balancing Environmental Concerns with the Need for Sterile Medical Devices

*Jack Brooksbank*

In December 2016, the Environmental Protection Agency (EPA) upgraded the hazard level of a chemical called ethylene oxide (ETO) from a “probable human carcinogen” to a “human carcinogen.”<sup>1</sup> Less than two years later, the EPA made public that it had found an elevated risk of cancer in the town of Willowbrook, Illinois.<sup>2</sup> Willowbrook is a village on the outskirts of Chicago with a population of approximately 8500—and had been, for decades, the home of an industrial plant that emitted approximately four thousand to seven thousand pounds of ETO per year.<sup>3</sup> The local reaction was swift and powerful. Citizens formed an advocacy group to shut down the plant.<sup>4</sup> The state attorney general filed a public nuisance suit against the operator of the Willowbrook plant: Sterigenics, LLC.<sup>5</sup> The Illinois legislature passed two laws further restricting the use of ETO.<sup>6</sup> Because of the new laws, the Illinois EPA overruled the operating permit Sterigenics needed to run the plant—temporarily shuttering the facility.<sup>7</sup>

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1. U.S. ENVIRONMENTAL PROTECTION AGENCY, EPA/635/R-16/350Fa, EVALUATION OF THE INHALATION CARCINOGENICITY OF ETHYLENE OXIDE (2016) [hereinafter EPA 2016].

2. AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, U.S. DEPT OF HEALTH & HUMAN SERVICES, LETTER HEALTH CONSULTATION (2018).

3. ILLINOIS EPA, STERIGENICS ANNUAL EMISSION REPORT (2017).

4. *See* STOP STERIGENICS, <https://www.stopsterigenics.com/> (last visited Apr. 11, 2020).

5. Complaint, *People v. Sterigenics*, No. 2018CH001329 (Ill. Cir. Ct 2018).

6. Ill. Pub. Act 101-0022, 415 Ill. Comp. Stat. 5/9.16 (2019), Ill. Pub. Act 101-0023, 415 Ill. Comp. Stat. 5/9.16 (2019).

7. Press Release, Illinois EPA, Illinois EPA Director Seals Portions of Sterigenics Due to Public Health Hazards from Ethylene Oxide Emissions (Feb. 15, 2019), [https://www2.illinois.gov/HISNews/19717-IEPA\\_Director\\_Seals\\_Portions\\_of\\_Sterigenics\\_Press\\_Release.pdf](https://www2.illinois.gov/HISNews/19717-IEPA_Director_Seals_Portions_of_Sterigenics_Press_Release.pdf). The Illinois EPA issued a “seal order” which, although not technically related to the then-current ETO release permit, prevented Sterigenics from using their ETO-based equipment. *Id.*; *see also* 5 Ill. Comp. Stat. 415/34(b) (2019) (granting the Illinois

The Illinois EPA eventually issued Sterigenics a new permit—reducing the allowable emissions at the facility from eighteen tons per year to just eighty-five pounds per year.<sup>8</sup> However, local resistance did not abate. The community continued to organize in opposition to the company.<sup>9</sup> Additional, stricter legislation regulating the use of ETO was proposed in the state legislature.<sup>10</sup> Resistance to the plant's reopening was so fierce that, just ten days after the reissuance of its operating permit, Sterigenics announced that it was closing the Willowbrook plant for good.<sup>11</sup>

While this action seemed like a clear victory for community organizing in some circles, in others it was ringing alarm bells. ETO is a clear, colorless gas that binds strongly to DNA molecules, but does not interact with most metals or plastics.<sup>12</sup> At close to room temperature<sup>13</sup> and in the absence of moisture or

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EPA the authority to close facilities or seal equipment if the agency finds “emergency conditions” exist).

8. ILLINOIS EPA, ID 043110AAC, Construction Permit, NESHAP Source (Sept. 20, 2019).

9. See, e.g., Ted Cox, *Stop Sterigenics Rips IEPA ETO Permit*, ONE ILLINOIS (Sept. 23, 2019), <https://www.oneillinois.com/stories/2019/9/23/stop-sterigenics-rips-iepa-permit-on-eto>.

10. ILH.B. 3888, 101st Ill. Gen. Assembly (2019) (documenting reaction of citizen group).

11. Michael Hawthorne, *Sterigenics Is Leaving Willowbrook, Eliminating Key Source of Cancer-Causing Ethylene Oxide in Chicago's Western Suburbs*, CHI. TRIBUNE (Sept. 30, 2019), <https://www.chicagotribune.com/news/environment/ct-sterigenics-ends-ethylene-oxide-operation-willowbrook-20190930-nkelcjskhkbawdhxx2snjk3oaxe-story.html>.

12. ALICE N. PARISI & WILLIAM E. YOUNG, *Sterilization with Ethylene Oxide and Other Gases*, in DISINFECTION, STERILIZATION, AND PRESERVATION, 580–95 (Seymour S. Block ed., 1991).

13. Most ETO sterilization takes place slightly above room temperature, between about forty and sixty degrees Celsius. GAMMA INDUSTRY PROCESSING ALLIANCE, *A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products* 29 (2017), [hereinafter GAMMA INDUSTRY PROCESSING ALLIANCE], <http://iiaglobal.com/wp-content/uploads/2018/01/White-Paper-Comparison-Gamma-Eb-Xray-and-EO-for-Sterilisation.pdf>. Steam sterilization, on the other hand, generally requires elevating the temperature to over 120 degrees Celsius. William A. Rutala, David J. Weber, & Healthcare Infection Control Practices Advisory Committee, *Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)* 59–60, CENTERS FOR DISEASE CONTROL AND PREVENTION (last updated May 2019).

radiation,<sup>14</sup> ETO is the most widely used sterilizing agent for medical devices in the country.<sup>15</sup> Indeed, for many types of medical devices, ETO is the only sterilization method currently available.<sup>16</sup> That is what Sterigenics performed at Willowbrook: it sterilized thousands of medical devices per day, from knee implants and pacemakers to syringes and surgical kits.<sup>17</sup>

Sterile medical devices are essential to the functioning of the American healthcare system, and access to sterile medical devices saves untold lives.<sup>18</sup> But there is not a great deal of excess sterilization capacity. Almost immediately upon closure of the plant, private industry groups and the federal government sounded the alarm about possible device shortages due to the closing of the Willowbrook plant.<sup>19</sup>

What could the federal government do in this situation? Indeed, which part of the federal government would act? The FDA seems like the obvious choice given the nature of the problem. But it was changes in environmental law that led to the Willowbrook plant closing in the first place, indicating that perhaps the EPA should be responsible. Given the complex and overlapping web of federal regulations, if the federal government decides to get involved, it is not clear which agency should act.

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14. Norman E. Sharpless, FOOD AND DRUG ADMINISTRATION, STATEMENT ON CONCERNS WITH MEDICAL DEVICE AVAILABILITY DUE TO CERTAIN STERILIZATION FACILITY CLOSURES (Oct. 25, 2019), <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures>.

15. *Id.*

16. *Id.*

17. FAQs, STERIGENICS, INC., <https://www.sterigenicswillowbrook.com/faqs> (last visited Feb 2, 2020).

18. Pre-sterilization surgeries had a mortality rate of up to forty-five percent, and even rudimentary sterilization cut that rate to approximately fifteen percent. Ulrich Tröhler, *Statistics and the British controversy about the effects of Joseph Lister's system of antisepsis for surgery, 1867–1890*, 108 J. R. SOC. MED. 280 (2015). Modern surgery has an overall mortality rate of around 0.71 percent. Anna Heeney et al., *Surgical Mortality - an Analysis of All Deaths Within a General Surgical Department* 12 SURGEON 121 (2014). Given that there were more than forty-eight million surgical procedures performed in the United States in 2010 alone, Margaret J. Hall et al., NATIONAL CENTER FOR HEALTH STATISTICS, AMBULATORY SURGERY DATA FROM HOSPITALS AND AMBULATORY SURGERY CENTERS: UNITED STATES, 2010 (February 28, 2017), and sterile medical devices are used for many procedures outside of surgery, the number of lives saved by sterilization is enormous.

19. See, e.g., Sharpless, *supra* note 14.

And even if an agency decides to attempt to intervene, it is not clear what they could actually do.

This Note attempts to determine whether any federal agencies could intervene to preempt state regulations of ETO. Part I of this Note introduces the relevant background information and the various regulatory schemes for ETO use and describes the general rules of how each statute handles preemption. Part II then analyzes whether the specific state regulations restricting the use of ETO for sterilizing medical devices are preempted under current federal law. This Note concludes that the balkanization of agency regulation prohibits agencies from making broad risk-risk balancing decisions outside their explicit mandate. Agencies should be given this power to prevent actions taken in one context from spilling over into another and causing serious consequences. The Clean Air Act should be amended, restricting the ability of states to pass regulations absent a preemption waiver from the EPA. This waiver should then generally be freely given—leaving the balance of state and federal power practically unchanged, unless and until the EPA finds that state action is endangering the public health.

## I. BACKGROUND

ETO is the most common sterilizing agent for medical devices due to its structure and specific reactivity.<sup>20</sup> However, those same properties mean that working with ETO is extremely dangerous.<sup>21</sup> While the effects of long-term ETO exposure are not well understood, scientists have long known that ETO is highly toxic—and scientific understanding of the long-term effects of exposure is growing more robust. Because of the high toxicity of ETO, it has long been regulated under a variety of federal statutes, each of which preempts state law to varying degrees.

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20. GAMMA INDUSTRY PROCESSING ALLIANCE, *supra* note 13 at 28.

21. Dennis W. Lynch et al., *Carcinogenic and Toxicologic Effects of Inhaled Ethylene Oxide and Propylene Oxide in F344 Rats*, 76 TOXICOLOGY AND APPLIED PHARMACOLOGY 69 (1984) (documenting the carcinogenic effects of ETO).

### A. ETO IS THE MOST WIDELY USED STERILANT FOR MEDICAL DEVICES

ETO is currently the most common method used to sterilize medical devices before use.<sup>22</sup> Currently, just over half of all medical devices in America are sterilized using ETO<sup>23</sup>—a total of approximately 20 billion individual devices per year.<sup>24</sup> Devices sterilized using ETO range from complex devices such as pacemakers<sup>25</sup> to simpler objects that many people may not even think of as medical devices, such as wound dressings.<sup>26</sup>

ETO is a small, volatile molecule with the chemical formula  $C_2H_4O$ .<sup>27</sup> At room temperature, ETO is a colorless gas.<sup>28</sup> The two carbon atoms and the oxygen atom form a three-member ring, making ETO a member of a class of compounds called epoxides.<sup>29</sup> Due to the inherent instability of such a small chemical ring, epoxides are known for being highly reactive.<sup>30</sup> ETO is no exception. ETO degrades quickly when dissolved in water, having a half-life of just twelve to fourteen days.<sup>31</sup> High concentration skin exposure to ETO may result in chemical

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22. GAMMA INDUSTRY PROCESSING ALLIANCE, *supra* note 13 at 28.

23. Sharpless, *supra* note 14.

24. Medline, Inc., *Facts About Ethylene Oxide, Medical Sterilization and Medline*, [https://newsroom.medline.com/wp-content/uploads/2018/11/EO-One-Pager.FINAL\\_-1.pdf](https://newsroom.medline.com/wp-content/uploads/2018/11/EO-One-Pager.FINAL_-1.pdf).

25. Thomas C. Crawford et al., *Cleaning and Sterilization of Used Cardiac Implantable Electronic Devices with Process Validation*, 3 J. AM. COLLEGE OF CARDIOLOGY: CLINICAL ELECTROPHYSIOLOGY 623, 626 (June 2017).

26. *Ethylene Oxide Sterilization for Medical Devices*, FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices#what> (last visited Feb. 1, 2020) [hereinafter *Ethylene Oxide Sterilization for Medical Devices*].

27. PUBCHEM, *Ethylene Oxide*, <https://pubchem.ncbi.nlm.nih.gov/compound/Ethylene-oxide#section=NIOSH-Analytical-Methods> (last visited Feb. 1, 2020).

28. *Id.*

29. *Id.*

30. Kathleen M. Morgan et al., *Thermochemical Studies of Epoxides and Related Compounds*, 78 J. ORGANIC CHEMISTRY 4303, 4303 (2013) (noting that epoxides “react readily”).

31. ENVIRONMENTAL PROTECTION AGENCY, EPA/600/8-84-009F, HEALTH ASSESSMENT DOCUMENT FOR ETHYLENE OXIDE at 1-1 (1985) [hereinafter EPA 1985]. Indeed, the reactivity of ETO means it can be controlled relatively easily: simply passing the used gas through acidified water causes it to break down into less volatile compounds. See CR CLEAN AIR GROUP, *Ethylene Oxide*, <https://www.crcleanair.com/pollutants/ethylene-oxide/> (last visited Jan. 31, 2020) [hereinafter CR CLEAN AIR GROUP].

burns.<sup>32</sup> In addition, it is highly flammable and potentially explosive.<sup>33</sup>

Despite the hazards, ETO is widely recommended as a sterilizing agent for medical devices.<sup>34</sup> This is due in part to the mechanism by which ETO sterilization works. The most common sterilization methods other than ETO are heat/steam- or radiation-based.<sup>35</sup> These methods are effective at killing microorganisms, but are often so harsh that they would destroy the device itself during sterilization.<sup>36</sup> ETO, on the other hand, functions by reacting with DNA molecules, disrupting the genome of any microorganisms present.<sup>37</sup> This allows device sterilization to proceed at near room temperature, and in the absence of moisture or radiation. ETO can therefore be used to sterilize devices that irradiation or heat treatment would damage. Indeed, for many types of devices, ETO is the only currently available sterilization method.<sup>38</sup>

#### B. THERE ARE CONCERNS OVER THE LONG-TERM TOXICITY OF ETO

In addition to being highly flammable, and acutely toxic in high concentrations, scientists and regulators have long expressed concerns over the health effects of long-term exposure to ETO.<sup>39</sup> After all, the chemical is widely used in the sterilization industry precisely because of its harmful effects on DNA. Studies performed on animals demonstrate that ETO has

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32. See PUBCHEM, *supra* note 27.

33. *Id.*

34. Rutala et al., *supra* note 13.

35. See GAMMA INDUSTRY PROCESSING ALLIANCE, *supra* note 13, at 8.

36. For example, many devices contain electronics that are moisture-sensitive. Irradiation also causes degradation in many of the types of polymers and plastics used in medical device manufacturing. See GAMMA INDUSTRY PROCESSING ALLIANCE, *supra* note 13, at 28.

37. PARISI & YOUNG, *supra* note 12.

38. Suzanne B. Schwartz & Elizabeth F. Claverie-Williams, *Preventing Medical Device Shortages by Ensuring Safe and Effective Sterilization in Manufacturing*, FOOD AND DRUG ADMINISTRATION (July 15, 2019), <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/preventing-medical-device-shortages-ensuring-safe-and-effective-sterilization-manufacturing>.

39. See, e.g., EPA 1985, *supra* note 31, at 1-3-1-8.

significant long-term carcinogenic effects.<sup>40</sup> However, scientific inquiries into the long-term effects of ETO exposure in humans have long been plagued with a paucity of data, making it difficult for researchers to draw strong conclusions.<sup>41</sup> This is due in large part to the obvious ethical problems of conducting direct human studies.<sup>42</sup> In 1985, EPA conducted a review of the effects of ETO exposure.<sup>43</sup> The agency concluded that ETO was a “probable human carcinogen.”<sup>44</sup> However, the agency stressed that its conclusion was based largely on a lack of quality data.<sup>45</sup>

Beginning in 2011, EPA undertook a second look at the toxicity of ETO as part of its Integrated Risk Information System (IRIS) process.<sup>46</sup> This reexamination was significantly more rigorous than the 1985 initial review due to the existence of additional studies on the effects of ETO performed after 1985. These included a number of additional animal studies.<sup>47</sup> The most important new data sources, however, were epidemiological studies linking ETO exposure to several forms of cancer in workers regularly exposed to ETO.<sup>48</sup> Additionally, the reevaluation used more complete guidelines for assessing the toxicity of chemicals, developed by the EPA in 2005.<sup>49</sup> As a result

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40. See, e.g., Lynch et al., *supra* note 21; H. Dunkelberg, *Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intra-gastric Administration to Rats*, 46 BRITISH J. CANCER 924 (1982).

41. Cf. R. E. Shore, M. J. Gardner, & B. Pannett, *Ethylene Oxide: An Assessment of the Epidemiological Evidence on Carcinogenicity*, 50 OCCUPATIONAL AND ENVTL. MED. 971 (1993) (failing to find a statistically significant relationship between occupational exposure to ETO and incidences of cancer).

42. EPA 1985, *supra* note 31, at 1-7.

43. See *generally id.*

44. *Id.* at 1-7.

45. *Id.*

46. See EPA 2016, *supra* note 1. IRIS is a comprehensive risk assessment program run by the EPA to evaluate the risk posed by environmental contaminants. *Basic Information About the Integrated Risk Information System*, ENVIRONMENTAL PROTECTION AGENCY, <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system> (last visited Jan. 31, 2020). IRIS studies are multistep affairs, including research of scientific literature, review by the EPA and other agencies, peer review by scientists, and the submission of public comments. *Id.* (navigate to the “IRIS Process” tab).

47. EPA 2016, *supra* note 1, at 3-20.

48. *Id.* at 3-14–3-19.

49. EPA, EPA/630/P-03/001F, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (2005) [hereinafter GUIDELINES FOR CARCINOGEN RISK ASSESSMENT].



of the reevaluation, the final report—published in 2016—upgraded the toxicity of ETO from “probable human carcinogen” to “human carcinogen.”<sup>50</sup> While this classification is solely informational, and alters no legal requirements,<sup>51</sup> the upgraded threat level brought more attention to the use of ETO. This prompted further investigation into the effects of ETO release, resulting in the findings of increased cancer risk that motivated state lawmakers to further restrict the use of ETO.<sup>52</sup>

### C. THE FEDERAL REGULATORY FRAMEWORK FOR ETO DIVIDES AUTHORITY BETWEEN DIFFERENT AGENCIES AND STATUTES

Due to its high toxicity and widespread use, the federal government has strictly regulated ETO since at least 1990.<sup>53</sup> However, there is no clear central regulatory scheme for the chemical. Rather, ETO is regulated on a “per context” basis. Thus at the federal level ETO is governed by at least two separate agencies under at least three separate statutes: the EPA under the Clean Air Act<sup>54</sup> (CAA); the Federal Insecticide, Fungicide, and Rodenticide Act<sup>55</sup> (FIFRA); and the FDA under the Food, Drug and Cosmetic Act<sup>56</sup> (FDCA).<sup>57</sup> Each of these statutes, and the accompanying regulations, deals with ETO use in different contexts.

#### i. Regulation by the EPA Under the Clean Air Act

In 1990, Congress, unhappy with what it perceived as a lack of effective agency action to regulate air pollutants, substantially

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50. See EPA 2016, *supra* note 1, at 1-1.

51. GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, *supra* note 49, at 1-2.

52. See AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, *supra* note 2 (stating that the EPA reexamined the health impact of the Willowbrook Sterigenics plant in part due to the increase in the threat assessment of ETO).

53. See Clean Air Act Amendments of 1990, Pub. L. 101-549, Nov. 15, 1990, 104 Stat. 2399.

54. 42 U.S.C. § 7401 (2018) et seq.

55. 7 U.S.C. § 136 (2018) et seq.

56. 21 U.S.C. § 301 (2018) et seq.

57. ETO is also governed by myriad state and local regulations. For example, the CAA allows delegation of a great deal of authority to state actors. 42 U.S.C. § 7410(a)(1) (2018). This Note focuses on the boundaries of federal legal authority and regulations. As such, more detail concerning the exact details of state’s laws falls beyond the scope.

amended the CAA.<sup>58</sup> These amendments increased the power of the EPA to regulate hazardous air pollutants,<sup>59</sup> and additionally set a schedule requiring the EPA to take action to regulate hazardous air pollutants.<sup>60</sup>

Congress set two methods for determining whether a given chemical is a “hazardous air pollutant” (HAP). First, a chemical could be listed directly in the statute.<sup>61</sup> Second, chemicals can be designated as a HAP if the EPA finds that the chemical creates a “human health hazard”<sup>62</sup> or would have “adverse environmental effects.”<sup>63</sup> If the EPA finds that a chemical meets either of those criteria, the EPA may designate it as a HAP through the rulemaking process.<sup>64</sup> ETO is one of the chemicals listed within the statute itself.<sup>65</sup>

Once a chemical is designated as a HAP, the EPA regulations list all of the categories of “major sources” or “area sources” of that pollutant.<sup>66</sup> Once a source category is listed, the agency must promulgate a National Emission Standard for Hazardous Air Pollutants (NESHAP) for that category.<sup>67</sup> Setting a NESHAP is a two-step technology-based process: first the EPA sets a regulatory “floor” determined by the best control technology currently in use, and then it considers whether an

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58. Clean Air Act Amendments of 1990, Pub.L. 101–549, Nov. 15, 1990, 104 Stat. 2399.

59. *Id.* § 301 (codified at 42 U.S.C. § 7412 (2018)).

60. *Id.* (amending 42 U.S.C. § 7412(c)(2), (e) 1990)).

61. 42 U.S.C. § 7412(b)(1) (2018). 189 specific chemicals were included within the statute. *Id.*

62. “Human health hazards” include substances “known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause[s] reproductive dysfunction, or which [are] acutely or chronically toxic.” *Id.* § 7412(b)(2).

63. “Adverse environmental effects” is less well-defined, but specifically mentions effects such as bioaccumulation. *Id.*

64. *Id.*

65. *Id.* § 7412(b)(1).

66. 42 U.S.C. § 7412(c)(1). A “major source” is a source that “has the potential” to emit ten or more tons of a single HAP, or twenty-five or more tons of any combination of HAPs. *Id.* § 7412(a)(1). Therefore a plant that, operating at full capacity, would release more than ten tons of a given HAP is a major source—regardless of whether it was, in fact, ever operated at full capacity. An “area source” is any stationary source that is not a “major source.” *Id.* § 7412(a)(2).

67. *Id.* § 7412(c)(2).

even higher degree of control would be feasible.<sup>68</sup> NESHAPs must be set at a level the agency determines to be the “maximum degree of reduction in emissions . . . achievable[.]” taking into account the costs of achieving such reductions and “any non-air quality health and environmental impacts.”<sup>69</sup> The CAA also sets minimum requirements for the stringency of these standards. For example, the standard for new emission sources (that is, sources constructed after the passage of the statute) must “not be less stringent than the emission control that is achieved in practice by the best controlled similar source.”<sup>70</sup>

The EPA completed this process for ETO in 1994.<sup>71</sup> It designated “sterilization facilities” as a category of pollution source and set a NESHAP for ETO release from those facilities.<sup>72</sup>

However, although the EPA sets minimum standards for HAPs, state actors are the primary enforcers of the CAA. The CAA invites states to submit a proposed State Implementation Plan (SIP).<sup>73</sup> These plans detail, among other requirements, how the state’s proposed enforcement mechanisms will ensure compliance with CAA standards.<sup>74</sup> The EPA then reviews the proposed SIP, and if the EPA is not satisfied that the SIP will ensure adequate pollution control, may either call for the SIP to be amended or reject it entirely.<sup>75</sup> In the absence of an adequate SIP, enforcement authority remains with the EPA, which will implement its own enforcement plan.<sup>76</sup> If satisfied, however, the EPA allows the SIP to go into effect, transferring primary

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68. See *Cement Kiln Recycling Coalition v. EPA*, 255 F.3d 855, 858 (D.C. Cir. 2001) (per curiam).

69. 42 U.S.C. § 7412(d)(2).

70. *Id.* § 7412(d)(3).

71. EPA, National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations, 59 Fed. Reg. 62585-01, 62589-601 (Dec. 6, 1994) (codified at 40 C.F.R. §§ 63.360-367).

72. 40 C.F.R. §§ 63.360-368 (2019); see also 40 C.F.R. § 63.10382 (2019) (in-hospital sterilization).

73. 42 U.S.C. § 7410(a)(1).

74. *Id.* SIPs must also contain enforceable emissions limits and technology standards for achieving those limits, provide for state monitoring programs to ensure compliance, demonstrate that local law enforcement will be adequately funded, require states to periodically report on emissions, detail the models the state is basing its decisions on, and set up a permitting process that charges sufficient fees to pay for itself. *Id.* § 7410(a)(2)(A)-(L).

75. *Id.* § 7410(k)(1)(B)-(k)(5).

76. *Id.* § 7410(c)(1).

enforcement authority to the state.<sup>77</sup> The EPA still retains authority to independently enforce the requirements set forth in the SIP, even absent state action.<sup>78</sup> Although the EPA cannot force a state to submit an SIP,<sup>79</sup> states that fail to do so can be sanctioned, for example, by the loss of some federal highway funding.<sup>80</sup> Currently, every state has submitted an SIP and been approved.<sup>81</sup> This is not a one-time approval, however. If the EPA learns of some deficiency later on, or suspects that the state is not living up to the necessary standards, the EPA must call for the SIP to be amended to address that concern.<sup>82</sup> Failure to address concerns raised by the EPA can then be grounds for revocation of state authority.<sup>83</sup> The EPA has issued numerous

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77. *Id.* § 7410(k)(3).

78. *Id.* § 7413.

79. “No matter how powerful the federal interest involved, the Constitution simply does not give Congress the authority to require the States to regulate.” *New York v. United States*, 505 U.S. 144, 178 (1992). This “anti-commandeering” principal forbids federal laws from requiring that a state take responsibility for implementing the federal CAA. *See id.* at 175 (stating that federal action that “commandeer[s]” state governments into the service of federal regulatory purpose is inconsistent with the “Constitution’s division of authority between federal and state governments”). However, Congress may use incentives to encourage states to cooperate with a federal program. *Id.* at 166 (“Our cases have identified a variety of methods, short of outright coercion, by which Congress may urge a State to adopt a legislative program with federal interests”). For example, “Congress may attach conditions on the receipt of federal funds.” *South Dakota v. Dole*, 483 U.S. 203, 206 (1987). These conditions may not be coercive. *See Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578 (2012) (discussing that a State needs to have a legitimate choice of “whether to accept the federal conditions in exchange for federal funds”). But, as long as the conditions do not reach this threshold, Congress can still “induce the States to adopt policies that the Federal Government itself could not impose.” *Id.* at 537 (citing *Dole*, 483 U.S. at 205–06).

80. 42 U.S.C. § 7509(a) (2018); 42 U.S.C. § 7410(m); *see also* 42 U.S.C. § 7509(b) (detailing the allowable sanctions).

81. *See* 40 C.F.R. Part 52 (listing all current SIPs).

82. 42 U.S.C. § 7410(k)(5).

83. *Id.* § 7410(c)(1)(A).

SIP calls;<sup>84</sup> however, such a call rarely results in full revocation of state authority.<sup>85</sup>

ii. Regulation by the EPA Under FIFRA

ETO is also regulated by the EPA as a pesticide under FIFRA. FIFRA defines “pesticide” as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”<sup>86</sup> “Pest” includes “any . . . fungus” and “any . . . virus, bacteria, or other microorganism.”<sup>87</sup> As a chemical sterilant used to destroy bacteria, ETO meets the definition.

FIFRA is primarily a registration-based statute. Its central provision is a prohibition on selling “any pesticide that is not registered under this [Act].”<sup>88</sup> Applicants for registration supply the agency with their proposed registrations and a full copy of the proposed labeling.<sup>89</sup> The registration will then be granted as long as the claims are supported by proper data and the labeling is found to be sufficient.<sup>90</sup> However, FIFRA still contains some controls over how pesticides are used. In addition to labeling, an applicant must supply the EPA with any controls it deems necessary.<sup>91</sup> The applicant supplies “any directions for its use.”<sup>92</sup>

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84. See, e.g., EPA, FACT SHEET: FINAL RULE—EMISSIONS MONITORING PROVISIONS IN STATE IMPLEMENTATION PLANS REQUIRED UNDER THE NO<sub>x</sub> SIP CALL (Feb. 2019), available at [https://www.epa.gov/sites/production/files/2019-02/documents/nox\\_sip\\_call\\_update\\_factsheet.pdf](https://www.epa.gov/sites/production/files/2019-02/documents/nox_sip_call_update_factsheet.pdf); EPA, STATE PLANS TO ADDRESS EMISSIONS DURING STARTUP, SHUTDOWN AND MALFUNCTION: FINAL ACTION ON RESPONSE TO PETITION FOR RULEMAKING, RESTATEMENT OF POLICY, FINDINGS OF INADEQUACY AND CALL FOR REVISIONS: FACT SHEET (May 22, 2015), available at <https://www3.epa.gov/airquality/urbanair/sipstatus/docs/20150522fs.pdf>.

85. There are currently eleven Federal Implementation Plans in effect. See EPA, *Basic Information About Air Quality FIPs*, <https://www.epa.gov/air-quality-implementation-plans/basic-information-about-air-quality-fips> (last visited Apr. 4, 2020) (listing all Federal Implementation Plans currently in effect). However, they are all relatively limited in scope, covering only portions of the CAA requirements. *Id.* For example, the federal government has taken over authority in Arkansas, but only as relating to interstate emissions of NO<sub>x</sub>. 40 C.F.R. § 52.184 (2020).

86. 7 U.S.C. § 136(u) (2018).

87. *Id.* § 136(t).

88. 7 U.S.C. § 136a(a) (2018).

89. *Id.* § 136a(c)(1).

90. *Id.* § 136a(c)(5).

91. *Id.* § 136a(c)(1)(C) & (E).

92. *Id.*

The EPA can also designate the chemical as a “restricted use pesticide.”<sup>93</sup> This chemical may then only be used under the supervision of a certified pesticide applicator.<sup>94</sup>

The EPA must also find that the chemical, when used to perform its “intended function . . . will not generally cause unreasonable adverse effects on the environment.”<sup>95</sup> In determining what constitutes an “unreasonable adverse effect on the environment,” the EPA must account for “the economic, social, and environmental costs and benefits of the use of any pesticide,” and must “weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.”<sup>96</sup>

ETO is currently registered under FIFRA for several uses.<sup>97</sup> ETO is a general use pesticide, subject to detailed labeling

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93. *Id.* § 136a(c)(1)(E), (d) (differentiating restricted use pesticides from general use pesticides, which are regulated less stringently).

94. *Id.* § 136a(d)(1)(C).

95. *Id.* § 136a(c)(5).

96. *Id.* § 136(bb).

97. EPA, EPA 738-R-08-003, REREGISTRATION ELIGIBILITY DECISION FOR ETHYLENE OXIDE (Mar. 2008), available at <https://archive.epa.gov/pesticides/reregistration/web/pdf/ethylene-oxide-red.pdf>.

requirements.<sup>98</sup> Firms using ETO for sterilization must provide all staff with health and safety training.<sup>99</sup>

### iii. Regulation by the FDA Under the FDCA

The FDCA grants the FDA regulatory authority over medical devices. “Devices” are defined as any “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” that is “intended for use in the diagnosis . . . or in the cure, mitigation, treatment, or prevention of disease . . . which does not achieve its primary

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98. ETO labeling must include a list of appropriate materials for personal protective equipment, directions for wearing protective equipment, directions for what to do if users of the chemical are directly exposed, recommendations for safe handling of the chemical, environmental hazards, information on what applications the chemical might be used for, risk mitigation steps, and a reference to EPA regulations governing minimum facility requirements. *Id.* at 48–54. Many of these directions require that the labeling contain the exact words chosen by the EPA. *Id.* For example, all ETO containers must bear a label stating that “[u]sers should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.” *Id.* at 52. The required labeling can also be fairly lengthy. For example, just one of the labels required to be on every ETO container must state the minimum level of personal protective equipment, and must read:

All handlers must wear at a minimum:

- > Long-sleeved shirt and long pants,
- > Shoes plus socks,
- > Chemical-resistant gloves, and
- > when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,
- > when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (positive-pressure) equipped with hood, helmet, or suit,
- > when the ambient ETO concentration is >2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- > Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- > Face-sealing goggles, a full face shield, or a full-face respirator.

*Id.* at 49–54.

99. *Id.* at 8, 24–25.

intended purposes through chemical action . . . .”<sup>100</sup> Critically for ETO, the definition of “device” includes finished medical devices as well as “any component, part, or accessory” of a finished device.<sup>101</sup> As a necessary part of the final, sterile device, ETO as a chemical sterilant is a device “component.” Thus, while a layman would not generally consider gases to be a “device,” as a necessary *component* ETO meets the legal definition of “device.” This classification grants the the FDA the power to ban the sale of any devices it deems to be “adulterated.”<sup>102</sup> One ground for determining that a product is adulterated is that it was manufactured using inadequate quality controls.<sup>103</sup>

The FDCA does not require the FDA to set specific manufacturing guidelines. However, the FDA does have direct authority to promulgate regulations governing the manufacturing of medical devices,<sup>104</sup> in addition to the adulteration guidelines. For the most part, the FDA relies on private industry standards for ETO sterilization.<sup>105</sup> These “voluntary consensus standards” contain model guidelines for the development and validation of ETO sterilization methods.<sup>106</sup> The FDA has also used its rulemaking authority to set more specific guidelines where it feels necessary.<sup>107</sup>

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100. 21 U.S.C. § 321(h) (2018).

101. *Id.*

102. 21 U.S.C. § 351(a).

103. *Id.*

104. 21 U.S.C. § 360j(f) (2018).

105. See *Ethylene Oxide Sterilization for Medical Devices*, *supra* note 26 (“Two voluntary consensus standards . . . describe how to develop, validate, and control ethylene oxide sterilization processes.”). The two standards are ANSI AAMI ISO 11135 (2014) and ANSI AAMI ISO 10993-7:2008(R) (2012). *Id.* See *generally Recognized Consensus Standards*, FDA (Dec. 23, 2019), [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/results.cfm?start\\_search=1&productcode=&category=Sterility&type=&title=&organization=&referencenumber=&regulationnumber=&recognitionnumber=&effectivedatetofrom=&effectivedateto=&pagenum=10&sortcolumn=pdd](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/results.cfm?start_search=1&productcode=&category=Sterility&type=&title=&organization=&referencenumber=&regulationnumber=&recognitionnumber=&effectivedatetofrom=&effectivedateto=&pagenum=10&sortcolumn=pdd) (listing recognized consensus standards for sterility).

106. *Ethylene Oxide Sterilization for Medical Devices*, *supra* note 26.

107. See, e.g., 21 C.F.R. §§ 880.6100, 880.6860 (2020) (providing performance standards for different ETO devices).



#### D. PREEMPTION OF STATE LAW REGULATIONS DIFFER BETWEEN FEDERAL STATUTES

All three federal regulatory statutes discussed above have express preemption provisions.<sup>108</sup> However, each statute handles preemption differently. The CAA has a very weak preemption clause that allows a great deal of leeway for state action.<sup>109</sup> FIFRA has a strong but narrow preemption clause, preempting all state regulation of only a few types of requirements.<sup>110</sup> And the FDCA has a very robust preemption clause, but one that is quite context-specific.<sup>111</sup>

##### i. The CAA Preempts Only State Standards that Are Less Strict than Federal Law

Environmental statutes such as the CAA are based upon “cooperative federalism[.]”<sup>112</sup> uniform federal laws address a number of weaknesses in existing state law, while still providing a broad role for state action so as to avoid over-extension of federal power. Federal laws helped to minimize the risk of “spillover effects” where pollutants emitted in one state primarily affect another.<sup>113</sup> Having one uniform standard also alleviated the risk of a “race to the bottom,” where in order to compete with one another for jobs, states eviscerated their environmental protections.<sup>114</sup> However, environmental laws

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108. 7 U.S.C. § 136v(b) (2018) (FIFRA); 21 U.S.C. § 360k(a) (2018) (FDCA); 42 U.S.C. § 7416 (2018) (CAA).

109. 42 U.S.C. § 7416.

110. 7 U.S.C. § 136v(b); *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 444 (2005).

111. 21 U.S.C. § 360k(a); *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502 (1996) (holding that FDCA preemption applies only where the state law is a requirement on a specific device).

112. *See, e.g., Jamie Gibbs Pleune, Do We Cair About Cooperative Federalism in the Clean Air Act?*, 2006 UTAH L. REV. 537, 540 (2006) (“The SIPs established a structure of cooperative federalism that reserved to the states the ability to meet the NAAQS according to their own policy choices”); Kim Ly, *Bates v. Dow Agrosciences: Overcoming Federal Preemption and Giving the People a Voice*, 29 J. OF THE NAT’L ASS’N OF ADMIN. L. JUDGES 297, 306 n.53 (2006) (“FIFRA encourages cooperation between federal and state in regulating pesticides.”).

113. Pleune, *supra* note 112 at 549.

114. Douglas R. Williams, *Cooperative Federalism and the Clean Air Act: A Defense of Minimum Federal Standards*, 20 ST. LOUIS PUB. L. REV. 67, 108–110 (2001); Douglas R. Williams, *Toward Regional Governance in Environmental Law*, 46 AKRON L. REV. 1047, 1074 (2013).

ultimately govern what uses of land are allowable, and “regulation of land use [is] a function traditionally performed by local governments.”<sup>115</sup> Thus, environmental laws such as the CAA raise concerns over federal overreach.

When passing the CAA, then, Congress designed the statute to preserve a central role for the states. The CAA is based on “cooperative Federal, State, regional, and local programs.”<sup>116</sup> States, not the federal government, still have the primary responsibility for ensuring compliance with CAA standards.<sup>117</sup> Under a system of cooperative federalism, states are given the first opportunity to regulate, as long as they at least meet the federal minimum standards.<sup>118</sup> States may adopt or enforce “any standard or limitation respecting emissions of air pollutants,” as long as they are not “less stringent” than the applicable federal standards.<sup>119</sup> From a purely legal point of view, state crackdowns on an environmental pollutant are simply business as usual, and there is nothing the EPA can do to prevent such state laws coming into effect. However, the CAA does potentially alter the remedies available. The CAA has been held to preempt federal common law remedies,<sup>120</sup> but the availability of state common law remedies for activities covered by the CAA remains uncertain.<sup>121</sup>

#### ii. FIFRA Preempts Only State Law Labeling Requirements

FIFRA takes a different approach to respecting state sovereignty than the CAA. Rather than set broad standards, with a broad allowance for state action, FIFRA preempts regulations of a narrow set of requirements. FIFRA strongly preempts states from enacting their own requirements in certain areas, such as labeling. The statute provides that a state “shall not impose . . . any requirements for *labeling or packaging* in

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115. *Hess v. Port Authority Trans-Hudson Corp.*, 513 U.S. 30, 44 (1994).

116. 42 U.S.C. § 7401(a)(4) (2018).

117. The CAA states that “air pollution prevention . . . and air pollution control at its source is the primary responsibility of the States and local governments.” *Id.* § 7401(a)(3); *see also supra*, Part I.C.i.

118. *See New York v. United States*, 505 U.S. 144, 167–68 (1992)

119. 42 U.S.C. § 7416 (2018).

120. *Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 424 (2011).

121. *See generally* Scott Gallisdorfer, *Clean Air Act Preemption of State Common Law: Greenhouse Gas Nuisance Claims After AEP v. Connecticut*, 99 VA. L. REV. 131 (2013).

addition to or different from those required under” FIFRA.<sup>122</sup> However, states are expressly allowed to regulate the use or sale of pesticides that have been registered under FIFRA, as long as those laws do not impact the labeling of the pesticide.<sup>123</sup>

Even under this seemingly strict preemption of state law in labeling, there may still be a role for state common law causes of action. Courts must engage in a fact-specific inquiry to determine whether state regulations genuinely impose requirements that are “in addition to” or “different from” those required under FIFRA.<sup>124</sup> But if the state law requirements are the same as those under FIFRA, then parties may still be able to sue under, for example, state law failure-to-warn claims.<sup>125</sup> Courts disagree regarding what constitutes uniformity with federal statutes.<sup>126</sup>

### iii. The FDCA Strongly Preempts State Law Regulation of Medical Devices

The FDCA expressly preempts any state law regulation of medical devices that “relate[] to the safety or effectiveness of the [medical] device,” or otherwise impose a requirement on the device.<sup>127</sup> Courts have held that this language narrows the scope of federal preemption.<sup>128</sup> Similarly to the requirements for FIFRA discussed above, state law requirements that are “different from, or in addition to” the federal requirements and “relate to safety and effectiveness” are preempted.<sup>129</sup> However, “parallel claims”—state law damages for actions that are already violations of federal law—are not preempted.<sup>130</sup>

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122. 7 U.S.C. § 136v(b) (emphasis added).

123. 7 U.S.C. § 136v(a) & (b).

124. *Bates v. Dow Agrosciences*, 544 U.S. 320, 444 (2005).

125. *Id.*

126. *Compare* *Indian Brand Farms, Inc. v. Novartis Crop Protection Inc.*, 617 F.3d 207, 221–25 (3d Cir. 2010) (holding that failure to warn claims are generally not preempted by FIFRA), *with* *In re Syngenta AG MIR 162 Corn Litigation*, 131 F. Supp. 3d 1177, 1207–08 (D. Kan. 2015) (holding that failure to warn claims are preempted under FIFRA).

127. 21 U.S.C. § 360k(a).

128. *See generally* *Lohr*, 518 U.S. at 486, 489–90, 496–98 (discussing how terms like “requirements” and “relating to [] safety and effectiveness” narrow the scope of preemptable state law).

129. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22 (2008).

130. *Id.* at 330; *see also* *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1205–07 (8th Cir. 2010).

The Supreme Court also held that the FDCA does not preempt state law claims for devices that reach the market without undergoing a full FDA safety review.<sup>131</sup> There are various pathways that would allow this to happen. The FDCA divides medical devices into three classes based on risk, with class I being low-risk devices and class III being high-risk.<sup>132</sup> Class III devices generally require a full pre-market review and FDA approval before they can be sold.<sup>133</sup> However, class I devices generally do not undergo any premarket review, as they are low-risk enough that they may be safely regulated with only general, post-market enforcement.<sup>134</sup> Class II devices are between these two, and a popular pathway to market class II devices is the so-called 510(k) process where a device is shown to be “substantially equivalent” to an already-approved device.<sup>135</sup> *Medtronic, Inc. v. Lohr* dealt with a class II device, and held that such a finding of substantial equivalence did not constitute an FDA review of its safety; therefore product liability claims for class II devices were not preempted.<sup>136</sup>

Some courts have also focused on whether the state law is a regulation of a specific medical device.<sup>137</sup> The FDA has embraced this approach, promulgating regulations stating that state laws are preempted “only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . .”<sup>138</sup> The regulation also states that “requirements of general applicability,” such as “general electric codes” are not preempted.<sup>139</sup> However, the Supreme Court has criticized this approach, stating that it “add[s] nothing to our analysis but confusion.”<sup>140</sup> The Court focused on the “parallel claims” analysis,<sup>141</sup> and courts since have generally found

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131. *Lohr*, 518 U.S. at 493.

132. 21 U.S.C. § 360c (2018).

133. *Id.* § 360e.

134. *Id.* § 360c(a)(1)(A).

135. *Id.* § 360c(a)(1)(B).

136. 518 U.S. at 493.

137. *Lohr*, 518 U.S. at 500; *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1372 (11th Cir. 1999).

138. 21 C.F.R. § 808.1(d).

139. *Id.* § 808.1(d)(1).

140. *Riegel*, 552 U.S. at 329.

141. *Id.* at 330.

preemption even if the claim brought could also be brought against other types of consumer products.<sup>142</sup>

Additionally, if states would like to promulgate their own medical device regulations, they can apply to the FDA for a waiver of federal preemption.<sup>143</sup> The FDA will grant a waiver as long as the state requirement is more strict than otherwise applicable federal law, the state law does not conflict with federal law, and the state law is “required by compelling local conditions.”<sup>144</sup> Once granted, the FDA may rescind the waiver upon making at least one of six possible factual findings.<sup>145</sup> These findings include a finding that new federal laws address the issue the state laws are aimed at, the “compelling local conditions” no longer exist, or that the state regulation is “no longer in the best interests of the public health.”<sup>146</sup>

## II. ANALYSIS

Despite the goal of protecting the health of its citizens, Illinois’ laws restricting ETO could easily have the opposite effect by causing dangerous medical device shortages.<sup>147</sup> However, despite the potentially catastrophic effects on the public’s access to effective medical treatments, currently there is most likely nothing the federal government could do to intervene. Due to the balkanization of federal authority, no single agency has the power to weigh the positive health impacts of ETO sterilization against the negative health consequences of worker and bystander exposure to the chemical.<sup>148</sup>

The CAA allows states to set their own environmental standards as long as they are at least as strict as the federal standards.<sup>149</sup> FIFRA preempts only state labelling

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142. See, e.g., *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at \*5 (M.D.N.C. Aug. 5, 2009); *Heisner v. Genzyme Corp.*, No. 08-C-593, 2009 WL 1210633, at \*2-3 (N.D.Ill. Apr. 30, 2009); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1300-03 (D. Colo. 2008).

143. 21 U.S.C. § 360k(b).

144. *Id.*; see also 21 C.F.R. §§ 808.53-.101 (2019) (listing all state waivers currently in effect, including the District of Columbia).

145. 21 C.F.R. §§ 808.35(b)(1)-(6) (2019).

146. *Id.*

147. See discussion *infra* Section II.A.

148. See discussion *infra* Section II.B.

149. 42 U.S.C. § 7416.

requirements, not regulations of the use of chemicals.<sup>150</sup> While FDA regulations preempt all state regulations of medical devices absent an approved waiver,<sup>151</sup> state environmental laws likely do not count as “requirements” for medical devices as they regulate only environmental release. It is therefore likely that no federal law preempts the new state-law controls on ETO.

#### A. STATE REGULATION OF ETHYLENE OXIDE COULD LEAD TO CRITICAL MEDICAL SHORTAGES AND ENDANGER PUBLIC HEALTH

The current state-level crackdown on the use of ETO has caused a great deal of alarm. The shutdown of the Willowbrook, Illinois facility discussed in the introduction section sent shockwaves throughout the medical industry. Attempts to further restrict the use of ETO for sterilization have not stopped with the Willowbrook shutdown. Recent state actions have also impacted the operations of at least four other sterilization facilities over concerns about the use of ETO.<sup>152</sup> Medical professionals are increasingly concerned that state overregulation could cause major device shortages or endanger the stability of the medical supply chain.<sup>153</sup> This instability could easily spread beyond just ETO, as well. Given the possible

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150. 7 U.S.C. § 136v(b).

151. 21 U.S.C. § 360k(a).

152. Ben Brasch, *State, Fulton Plant Make Deal to Reduce Ethylene Oxide Emissions*, ATLANTA JOURNAL-CONSTITUTION (Jan. 8, 2020), <https://www.ajc.com/news/local/state-fulton-plant-make-deal-reduce-ethylene-oxide-emissions/uOqcQ3tTc2MaeaFkWzstCN/>; Maria Fontanazza, *Another ETO Medical Device Sterilizer to Close Due to Environmental Quality Issues*, MEDTECH INTELLIGENCE (Apr. 1, 2019), [https://www.medtechintelligence.com/news\\_article/another-eto-medical-device-sterilizer-to-close-due-to-environmental-quality-issues/](https://www.medtechintelligence.com/news_article/another-eto-medical-device-sterilizer-to-close-due-to-environmental-quality-issues/); Brenda Goodman & Andy Miller, *Metro Atlanta Sterilizing Plant Shutting Down as Air Tests Begin; Lawsuit Challenges EPD Deal*, WABE (Sept. 9, 2019), <https://www.wabe.org/metro-atlanta-sterilizing-plant-shutting-down-as-air-tests-begin-lawsuit-challenges-epd-deal/>; Conor Hale, *Georgia Files Restraining Order Against BD Sterilization Plant over Ethylene Oxide Leak*, FIERCE BIOTECH (Oct. 24, 2019 6:25am), <https://www.fiercebiotech.com/medtech/georgia-files-restraining-order-against-bd-sterilization-plant-over-ethylene-oxide-leak/>; Press Release, VIANT, <https://tribwxmi.files.wordpress.com/2019/03/viant-letter-1.pdf> (discussing the closure of sterilization operations at a Grand Rapids facility due to concerns surrounding air quality).

153. See, e.g., Fontanazza, *supra* note 152; David Lim, *Ethylene Oxide Plant Closures Put US on ‘Cusp of a Major Medical Logistical Failure’*, MEDTECH DIVE (Nov. 8, 2019), <https://www.medtechdive.com/news/ethylene-oxide-plant-closures-place-united-states-on-cusp-major-medical-logistical-failure/566922/>.

overreaction to fears of chemical toxicity, coupled with human irrationality in the face of uncertainty, these issues could reoccur with another vital chemical unless a permanent solution is found.

The FDA has been following the issue closely, and issued a statement warning of potentially drastic medical device shortages.<sup>154</sup> Numerous industry actors have also sounded the alarm, stating that the remaining sterilization facilities do not have the capacity to keep up with demand.<sup>155</sup> Indeed, the closure of the Sterigenics Willowbrook facility has already caused shortages of some types of devices that used to be processed there.<sup>156</sup>

Recent history has also shown the potential fragility of the medical supply chain in the United States. Puerto Rico manufactures approximately eight percent of the pharmaceuticals used in the United States, as well as huge numbers of medical devices.<sup>157</sup> Hurricane Maria hit Puerto Rico in late 2017, causing widespread devastation across the

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154. See Sharpless, *supra* note 14.

155. See, e.g., Lim, *supra* note 153; MedTech Intelligence Staff, *What Industry Is Saying About Proposed Ethylene Oxide Sterilization Ban*, MEDTECH INTELLIGENCE (Nov. 8, 2019), [https://www.medtechintelligence.com/news\\_article/what-industry-is-saying-about-proposed-ethylene-oxide-sterilization-ban/](https://www.medtechintelligence.com/news_article/what-industry-is-saying-about-proposed-ethylene-oxide-sterilization-ban/) (voicing concerns that closures could severely impact other sterilization facilities and would “send our healthcare supply chain into a tailspin . . .”); ECRI Institute, *ECRI Institute Opposes Proposed Ban of Ethylene Oxide (ETO) Sterilization Operations* (Nov. 7, 2019), <https://www.ecri.org/press/ecri-institute-opposes-proposed-ban-ethylene-oxide-sterilization> (indicating that ECRI Institute, a non-profit patient safety organization, opposes a proposed ban on ETO sterilization operations because it “could result in widespread shortages of sterile medical devices”).

156. Jeffrey E. Shuren, Dir. CDRH Offices: Office of the Center Director, FDA, Statement From Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on Agency Efforts to Mitigate Temporary Shortage of Pediatric Breathing Tubes Due to Recent Closure of Illinois Sterilization Facility (Apr. 12, 2019), <https://www.fda.gov/news-events/press-announcements/statement-jeff-shuren-md-director-center-devices-and-radiological-health-agency-efforts-mitigate>.

157. Measured per dollar amount of product. See FDA, SECURING THE FUTURE FOR PUERTO RICO: RESTORING THE ISLAND’S ROBUST MEDICAL PRODUCT MANUFACTURING SECTOR, <https://www.fda.gov/files/about%20fda/published/Securing-the-Future-for-Puerto-Rico—Restoring-the-Island%27s-Robust-Medical-Product-Manufacturing-Sector.pdf>.

island.<sup>158</sup> Beyond just the effect of the storm on the island, however, the disruption of the medical manufacturing industry led to widespread shortages of critical medical supplies across the United States.<sup>159</sup> Some of these shortages lasted for multiple years.<sup>160</sup> And with over fifty percent of medical devices being sterilized with ETO,<sup>161</sup> potential shortages from lack of sterilization capacity could be severe indeed. Past shortages have caused the price of scarce supplies to increase up to tenfold.<sup>162</sup> This limits patient access and contributes to the already skyrocketing price of healthcare.

Nor are such medical supply shortages merely business problems. Medical shortages have had a long history of adversely affecting patient care.<sup>163</sup> While it is difficult to track exactly what causes a particular patient outcome, many experts have commented on the increased risk to patients caused by

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158. Amanda Holpuch & Hazar Kilani, *Hurricane Maria's Lasting Impact on Puerto Rico's Children Revealed in Report*, GUARDIAN (Apr. 26, 2019), <https://www.theguardian.com/world/2019/apr/26/hurricane-maria-puerto-rico-youth-mental-health-study-report> (reporting on long-term effects of Hurricane Maria, including physical and mental health impacts); Frances Robles, *Puerto Rican Government Acknowledges Hurricane Death Toll of 1,427*, N. Y. TIMES (Aug. 9, 2018), <https://www.nytimes.com/2018/08/09/us/puerto-rico-death-toll-maria.html>.

159. See, e.g., Katie Thomas & Sheila Kaplan, *Hurricane Damage in Puerto Rico Leads to Fears of Drug Shortages Nationwide*, N.Y. TIMES (Oct. 4, 2017), <https://www.nytimes.com/2017/10/04/health/puerto-rico-hurricane-maria-pharmaceutical-manufacturers.html> (describing the shortage of pharmaceuticals across the United States following a hurricane in Puerto Rico); Lauren Weber, *Hurricane Maria's Effect on the Health Care Industry Is Threatening Lives Across the U.S.*, HUFFPOST (Sept. 20, 2018, 5:45 am), [https://www.huffpost.com/entry/iv-bag-drug-shortage-puerto-rico-hurricane-maria\\_n\\_5ba1ca16e4b046313fc07a8b](https://www.huffpost.com/entry/iv-bag-drug-shortage-puerto-rico-hurricane-maria_n_5ba1ca16e4b046313fc07a8b) (describing the shortage of saline IV bags following the same hurricane).

160. David Lim, *B. Braun Invests \$1B in IV Fluid Manufacturing to Alleviate Shortages*, MEDTECH DIVE (May 15, 2019), <https://www.medtechdive.com/news/b-braun-invests-1b-in-iv-fluid-manufacturing-to-alleviate-shortages/554855/> (reporting that even almost two years after Hurricane Maria, there are still shortages of IV bags).

161. GAMMA INDUSTRY PROCESSING ALLIANCE, *supra* note 13, at 9; OSHA, REGULATORY REVIEW OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION'S ETHYLENE OXIDE STANDARD at II-11, Mar. 2005.

162. See Weber, *supra* note 159 (describing an ambulance service that has "had to pay up to 10 times what it normally would for certain medication-infused saline bags because of the short supply")

163. *Id.* (providing one recent example in the aftermath of Hurricane Maria).



supply shortages.<sup>164</sup> For example, the shortages caused by Hurricane Maria led to many medical providers having to change how they treated common injuries and illnesses, increasing health risks as patients received non-standard care.<sup>165</sup> The practice of switching to different treatments itself went on to create further shortages of the supplies used in the second-best procedures.<sup>166</sup> Other studies of medical shortages found evidence of severe rationing, where patients were unable to receive the treatments they needed.<sup>167</sup> One study directly found that the shortage of a critical drug “was significantly associated with increased mortality among patients . . .”<sup>168</sup> Past problems with inadequate sterilization have also led to fatal infections in patients receiving the substandard replacement devices.<sup>169</sup>

The potential shortages caused by a lack of sterilization capacity could be further exacerbated by foibles of human psychology. People do not always behave rationally when

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164. See Andrew Hantel et al., *Prevalence and Severity of Rationing During Drug Shortages*, 179 JAMA INTERNAL MED. 710, 710 (2019) (“Hospital medication shortages in the United States are associated with decreased quality and/or quantity of life.” (internal citations omitted)); C. Lee Ventola, *The Drug Shortage Crisis in the United States*, 36 PHARMACY & THERAPEUTICS 740, 740 (2011) (“[Drug shortages] adversely affect patient care by causing substitution of safe and effective therapies with alternative treatments; compromising or delaying medical procedures; or causing medication errors.”).

165. Weber, *supra* note 159 (explaining that due to the shortages of IV bags, hospitals and doctors had to deviate from standard medical practice).

166. *Id.* (“[T]he lack of IV bags led to ‘a large number of downriver shortages, . . .’”) (quoting Erin Fox, senior director of the University of Utah’s drug information services); C. Lee Ventola, *supra* note 164, at 752 (“[T]he original shortage causes a decline in the supply of an alternative agent because of an unexpected increase in demand.”) (internal citation omitted).

167. See C. Lee Ventola, *supra* note 164, at 750–51.

168. Emily Vail et al., *Association Between US Norepinephrine Shortage and Mortality Among Patients with Septic Shock*, 317 JAMA 1433, 1434 (2017).

169. See Chad Terhune, *Olympus Told Its U.S. Executives No Broad Warning About Tainted Medical Scopes Was Needed, Despite Superbug Outbreaks*, L.A. TIMES (July 24, 2016), <https://www.latimes.com/business/la-fi-olympus-scopes-emails-20160721-snap-story.html> (reporting that “at least [thirty-five] people at U.S. hospitals have died since 2013 . . . after suffering infections from contaminated gastrointestinal scopes . . .”); FDA, *Infections Associated with Reprocessed Duodenoscopes*, <https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes> (last updated Aug. 29, 2019) (“[C]ases of [patient-to-patient transmission of] infection were occurring despite confirmation that the users [of duodenoscopes] were following proper manufacturer cleaning and disinfection or sterilization instructions.”).

confronted with a crisis.<sup>170</sup> Faced with uncertainty and shortages, organizations and individuals often decide to hoard resources and over-order supplies in order to create a stockpile.<sup>171</sup> This stockpiling behavior creates a spike in demand of the scarce resource, contributing to, or even creating, the very problem that it was meant to alleviate. For example, the UK has experienced a number of consumer goods shortages, caused entirely by over-purchasing by consumers worried access might become limited due to Brexit.<sup>172</sup> Coronavirus fears caused such widespread panic buying that many Australian supermarkets discussed limiting purchases of toilet paper—a product produced locally that is, according to many experts, at no risk of any shortages.<sup>173</sup> There have even been a number of drug shortages caused by rumors of price increases, as hospitals try to stock up before the potential cost hike.<sup>174</sup> This is a particularly likely scenario given the uncertainty stemming from the lack of uniform regulations at play with ETO.

The controversy surrounding ETO may expand to include other chemicals, further endangering the American healthcare system. There have been several recent instances where commonly-used chemicals have, upon further study, been found to be potentially harmful.<sup>175</sup> Some of these chemicals also

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170. See, e.g., Amos Tversky & Daniel Kahneman, *Availability: A Heuristic for Judging Frequency and Probability*, 5 COGNITIVE PSYCHOL. 207, 208–09 (1973) (discussing the availability heuristic, which is a mental shortcut used in determining the likelihood of an event based on past experiences; events that one encounters frequently are viewed as more likely to reoccur than events one encounters infrequently, even if statistically the infrequent encounters occur more often).

171. C. Lee Ventola, *supra* note 164, at 749.

172. Tim Wallace, *Panic Buying for Brexit Risks Causing the Very Shortages Stockpilers Fear, Warns OBR*, TELEGRAPH (Mar. 19, 2019), <https://www.telegraph.co.uk/business/2019/03/19/panic-buying-risks-causing-shortages-stockpilers-fear-warns/>.

173. Frances Mao, *Coronavirus Panic: Why Are People Stockpiling Toilet Paper?*, BBC NEWS (Mar. 4, 2020), <https://www.bbc.com/news/world-australia-51731422>.

174. See C. Lee Ventola, *supra* note 164, at 749.

175. See, e.g., Julia Barrett, *Hormone Impact: BPA Linked to Altered Gene Expression in Humans*, 119 ENVTL. HEALTH PERSP. 524 (2011) (BPA); Karen Duderstadt, *Chemicals in Daily Life: Emerging Evidence on the Impact on Child Health*, 26 J. OF PEDIATRIC HEALTH CARE 155 (2012) (BPA); Thit A. Mørck et al., *PFAS Concentrations in Plasma Samples from Danish School Children and Their Mothers*, 129 CHEMOSPHERE 203 (2015) (PFAS).

engendered a high degree of public scrutiny.<sup>176</sup> While many of these chemicals pose a genuine public health danger, public reaction has verged on frenzy instead of measured and constructive dialog. One article discussing BPA, a chemical previously used in some plastics that had been linked to potential reproductive issues, used the lurid title “BPA Wrecks Sex, Fouls Food—and Worse” in an attempt to capture attention and internet traffic.<sup>177</sup> There is now an entire scientific literature dealing with “chemophobia”—the overreaction to risks associated with anything described as a “chemical.”<sup>178</sup>

This propensity to overreaction, coupled with the inherent toxicity of chemical sterilants, leaves the American medical industry vulnerable. The medical system needs the ability to sterilize devices which cannot withstand high temperatures or prolonged exposure to radiation. Yet any chemical that could replace ETO would itself need to be toxic enough to destroy bacteria—and therefore would very likely cause many of the same side effects, and inspire similar levels of opposition, as ETO itself. A more thoughtful regulatory response is therefore required to prevent serious shortages of lifesaving materials.

#### B. UNDER CURRENT LAW, STATE LAW REGULATIONS OF ETO ARE LIKELY NOT PREEMPTED

By dividing regulatory authority over ETO into separate contexts, Congress unwittingly prevented any single agency from being able to consider the ultimate issue at stake: whether the benefits to the public health outweigh the harms caused by ETO use. Current environmental laws such as the CAA are based upon assessments of the health impact only from the

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176. See, e.g., Paula Gardner, *Michigan Sues 17 Chemical Companies for PFAS Contamination*, MLIVE (Jan. 14, 2020), <https://www.mlive.com/news/2020/01/michigan-sues-17-chemical-companies-for-pfas-contamination.html>; Michael Hawthorne & Dan Mihalopoulos, *Chicago Sends a Message on BPA*, CHI. TRIB. (May 14, 2009), <https://www.chicagotribune.com/news/ct-xpm-2009-05-14-0905131100-story.html>.

177. Elaine Shannon, *BPA Wrecks Sex, Fouls Food—and Worse*, ENVTL. WORKING GROUP (Nov. 11, 2009), <https://www.ewg.org/kid-safe-chemicals-act-blog/2009/11/bpa-ruins-sex-pollutes-food-and-probably-worse/>.

178. See, e.g., Susan Billington et al., *Covert Approaches to Countering Adult Chemophobia*, 85 J. CHEMICAL EDUC. 379 (2008); Michelle Francl, *How to Counteract Chemophobia*, 5 NATURE CHEMISTRY 439 (2013); Gordon Gribble, *Food Chemistry and Chemophobia*, 5 FOOD SECURITY 177 (2013).

release of the pollutant, excluding any consideration of what the chemical is used for.<sup>179</sup> Based on this narrow analytical foundation, states are given authority to regulate more strictly.<sup>180</sup> The architects of the CAA assumed that stricter regulations would lead to better health outcomes, and states are granted the authority to choose to adopt more costly measures, if they wish.<sup>181</sup> Medical device regulations, on the other hand grant the states far less authority to set their own regulations.<sup>182</sup> However, while the FDA can set minimum standards for compounds all the way up the supply chain, it does not have the power to assure that a given compound remains available. There is therefore most likely no formal action that a federal agency could take to prevent the state-level banning of ETO.

i. State Regulations of ETO Are Likely Not Preempted by EPA Authority

The CAA is very clear: states can pass their own emission limits as long as they are more stringent than their federal equivalents.<sup>183</sup> FIFRA is equally clear: state regulations of the *use* of pesticides are not preempted.<sup>184</sup> States are only forbidden from passing laws altering the requirements for pesticide labels.<sup>185</sup> State laws banning the use of ETO are more strict than current federal laws, thus evading CAA preemption. And state laws ban only the use, and do not add any requirements for the labeling, thus evading FIFRA preemption. Therefore, neither the CAA nor FIFRA preempt state law bans on the use of ETO.

ii. State Environmental Laws Are Likely Not Specific Enough to Devices to Be Preempted Under the FDCA.

The FDCA contains a much stronger preemption clause than those in the CAA and FIFRA.<sup>186</sup> However, that preemption has been interpreted relatively narrowly, with courts generally reading it as only applying to laws that directly affect the safety

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179. See *Cement Kiln Recycling Coalition v. EPA*, 255 F.3d 855, 858 (D.C. Cir. 2001) (per curiam).

180. 42 U.S.C. § 7416.

181. *Id.*

182. 21 U.S.C. § 360k(a).

183. 42 U.S.C. § 7416.

184. 7 U.S.C. § 136v(a) & (b).

185. *Id.* § 136v(b).

186. 21 U.S.C. § 360k.

or effectiveness of the device.<sup>187</sup> State environmental regulations are therefore likely not specific enough to any given device to constitute a “requirement” for the device. The FDCA therefore likely does not preempt such attenuated, indirect effects.

The FDCA does not envision as broad a role for state policies as environmental statutes generally do. It preempts all state law requirements for medical devices—regardless of whether they are stricter than federal law.<sup>188</sup> However, the federalism and state sovereignty concerns motivating the design of environmental law are still present with device regulations.<sup>189</sup> Courts have therefore narrowed the interpretation of the FDCA’s preemption provisions.<sup>190</sup>

A partly analogous context may be found in the realm of product liability cases. Where a consumer brings a product liability case against a medical device manufacturer, the manufacturer often raises preemption as a defense.<sup>191</sup> The argument is that because the FDA has certified the device as safe, state law cannot hold that the device unreasonably caused injury—i.e. was unsafe.<sup>192</sup> Where the product at issue has been subject to FDA review for safety, courts have found in favor of preemption.<sup>193</sup>

Applying this reasoning to the context of environmental regulations directed at ETO, however, leads to difficulties. First, preemption under this reasoning would apply only where the FDA has actually reviewed the device in question; class I and class II devices may not be covered.<sup>194</sup> Even assuming that every affected facility will process at least some class III devices,

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187. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486, 489–90, 496–98 (1996) (discussing how terms like “requirements” and “relating to [] safety and effectiveness” narrow the scope of preemptable state law).

188. *Id.*

189. *See Lohr*, 518 U.S. at 475 (discussing the broad police powers states have to protect the health and safety of its citizens) (citing *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)).

190. *Lohr*, 518 U.S. at 493–94 (holding that “[FDCA’s § 510(k) “substantial equivalency”] process is focused on *equivalence*, not safety”) (internal quotations omitted).

191. *See, e.g., id.*

192. *Id.*; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008).

193. *See, e.g., Riegel*, 552 U.S. at 330.

194. *Cf. Lohr*, 518 U.S. at 493 (holding that common law claims regarding a class II device are not preempted because there was no actual FDA review of safety for that specific device).

however, the analogy still does not hold. For a class III device, the thing that is reviewed by the FDA is the final, commercially sold device, not the sterilants used in its manufacture.<sup>195</sup> More directly, while a product liability claim directly contradicts the FDA certification that the device is safe, an environmental regulation raises no such issue. A product liability claim (“Device A is unsafe”) is directly incompatible with the federal law (“Device A is safe”). However, a law deeming a specific device safe does not contradict a law preventing the release of a chemical used in manufacturing that device. A necessary consequence of banning that release could be that the chemical is unavailable for use in manufacturing. But the law banning the release can hardly be said to be a “requirement” on the device.

That the FDCA likely does not preempt state environmental regulation is further reinforced by the language of the FDCA. State lawmakers are forbidden from creating requirements different from those “applicable under this chapter [of the FDCA].”<sup>196</sup> An environmental law requirement could impact the safety of a device and therefore be construed as applicable under the FDCA. However, including the language preempting state requirements that differs from those “applicable under this chapter [of the FDCA]” shows that the FDCA preempts only more direct requirements relating to medical devices rather than indirect impacts from unrelated environmental legislation. Since a state law banning the release of ETO is most likely not a “requirement” of the manufacture of any particular medical device, it would most likely not be preempted by the FDCA.

### C. FEDERAL AGENCIES SHOULD HAVE A WAY TO OVERSEE REGULATION OF NECESSARY HEALTHCARE CHEMICALS LIKE ETHYLENE OXIDE

States have a strong and legitimate interest in regulating the quality of their environments. However, sometimes actions that protect the public health implicate other important health programs. The use of harsh chemicals to prepare safe medical devices may have a negative impact on public health,<sup>197</sup> but that impact may be far outweighed by the need for sterile products.

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195. See, e.g., 21 U.S.C. § 360c(C) (referring to “a device” as a whole, not the specific contents used in the manufacture such device).

196. *Id.* § 360k(a)(1).

197. Recall that ETO has been deemed a “human carcinogen.” EPA 2016, *supra* note 1.

To prevent a situation where every state actor chases purely local goals at the expense of nationwide public health, the federal government should have a role to ensure national values are represented.

One way to look at the problem of ETO sterilization is through the lens of NIMBY (“not in my backyard”), a sort of inverse tragedy of the commons.<sup>198</sup> In a NIMBY<sup>199</sup> situation, where there is widespread agreement on the importance of a particular endeavor, and each actor agrees that it needs to be done somewhere, but each actor wants it to be done somewhere else.<sup>200</sup> When a multitude of different local actors regulate ETO, each locality has an incentive to strenuously resist the operation of any sterilization facilities, acting under the belief that some other locality will allow it. A uniform federal system of regulations could help to solve this problem, as a national perspective eliminates the possibility that someone else will do it. A facility being operated anywhere in the United States would be subject to the same rules.

Additionally, a uniform regulatory system may alleviate some causes of the NIMBY reaction. Some academics suggest that the true cause of the depth of NIMBY feeling is concerns of fairness.<sup>201</sup> “The aim of NIMBY activists and actors can be seen as not only protesting against planning processes, but . . . ensuring the legitimacy and acceptability of land-use

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198. A tragedy of the commons is where every person agrees there should be limits on the use of a resource, but are individually better off by not following any limits, leading to the over-exploitation of the resource to the point of destruction. Garrett Hardin, *The Tragedy of the Commons*, 162 *SCIENCE* 1243 (1968) (offering various illustrations of the concept).

199. NIMBY has also been referred to as LULU (“locally unwanted land uses”), NIABY (“not in anyone’s backyard”), NIMTOO (“not in my term of office”), BANANA (“build absolutely nothing anywhere near anyone”), NOPE (“not on planet earth”), and CAVE (“citizens against virtually everything”). Carissa Schively, *Understanding the NIMBY and LULU Phenomena: Reassessing Our Knowledge Base and Informing Future Research*, 21 *J. PLAN. LITERATURE* 255 (2007).

200. Patrick Devine-Wright, *Explaining “NIMBY” Objections to a Power Line: The Role of Personal, Place Attachment and Project-Related Factors*, 45 *ENV. & BEHAV.* 761, 763–65 (2012); Renée J. Johnson & Michael J. Scicchitano, *Don’t Call Me NIMBY: Public Attitudes Toward Solid Waste Facilities*, 44 *ENV. & BEHAV.* 410, 410–12 (2012).

201. Veikko Eranti, *Re-Visiting NIMBY: From Conflicting Interests to Conflicting Valuations*, 65 *SOC. REV.* 285, 286 (2017); Maarten Wolsink, *Invalid Theory Impedes Our Understanding: A Critique of the Persistence of the Language of NIMBY*, 31 *TRANSACTIONS INST. BRIT. GEOGRAPHERS* 85 (2006).

decisions on a larger scale.”<sup>202</sup> A federal regulatory scheme attuned to the actual issue, namely whether the overall health benefit of ETO use outweighs the hazards of that use, could help alleviate these concerns. Strong federal controls of ETO use would ensure that any continuing use of ETO would reflect the considered expert judgment of a specialized agency. Further, if local residents become concerned and wish to gain a more thorough understanding of ETO regulation, a single federal standard would be much easier to find and understand than an overlapping collage of local, state, and federal laws and regulations.

#### D. AMENDING THE CAA TO INCLUDE FDA-LIKE PREEMPTION ALLOWS STATE FLEXIBILITY AND WOULD PREVENT SHORTAGES OF MEDICAL DEVICES

Federal agencies should play a greater role in the uniform regulation of ETO. Such a change could take many forms. One promising possibility is a preemption waiver system based on the existing medical device laws. An FDA-style preemption system, where states can apply for a waiver of federal preemption, could balance the interests of state autonomy versus federal uniformity.<sup>203</sup> A waiver system would allow for state flexibility in setting their own laws, while still allowing the federal government to intervene if it determined that local efforts would ultimately cause more harm than good. Lastly, granting this role to the EPA would make the most sense, because the EPA is already involved in CAA rulemaking.

Under the current FDCA waiver system, a state may obtain a waiver as long as the proposed state requirement is stricter than applicable federal standards, the state law does not directly conflict with federal law, and the state law is “required by compelling local conditions.”<sup>204</sup> Ordinarily, an environmental law passed to ensure the safety of the local populace is certainly

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202. Eranti, *supra* note 201, at 287.

203. The current waiver system does already apply to ETO—to the extent that state laws are currently preempted by the FDCA. As state environmental laws are most likely not preempted under the FDCA, *see supra* Section I.D.iii, statutory change will be necessary to include these types of laws under any potential preemption waiver scheme.

204. 21 U.S.C. § 360k(b); *see also* 21 C.F.R. §§ 808.53–.101 (2019) (listing all state waivers currently in effect).



“compelling.”<sup>205</sup> Under this system, preemption waivers could be given freely, leaving the state’s inherent powers to protect its population mostly intact.

The current FDA waiver system allows a revocation of a granted waiver if the agency makes at least one of several specified findings.<sup>206</sup> Specifically, the FDA can revoke a granted preemption waiver upon a finding that the state law is “no longer in the best interests of the public health.”<sup>207</sup> Importing this language to a preemption system under the CAA for chemical sterilants such as ETO would grant the federal government a mechanism by which it could intervene to prevent critical shortages of medical products. It would also prevent too much federal intrusion into state policymaking. After all, a mere increase in price would not affect the public health, so increased regulatory burden alone would not be enough to trigger a revocation of the state preemption waiver.<sup>208</sup> As long as a state law did not threaten medical device shortages—if, for example, it were phased in over a long enough period of time that the supply chain could adapt and ensure uninterrupted production—states would be free to make whatever local law choices they desired.

Granting this authority to the EPA would make the most sense. The state laws that are causing these issues are environmental statutes, an area of the EPA’s expertise.<sup>209</sup> Unlike the FDA, the EPA is already involved in CAA rulemaking. Taking the time to better understand states’ proposals would therefore be less of a burden. Indeed, due to the existing CAA preemption provisions,<sup>210</sup> the EPA is likely already well-informed about state environmental laws.

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205. *Cf. Houston Chronicle Publ’g Co. v. City of League City, Tex.*, 488 F.3d 613, 622 (5th Cir. 2007) (holding that public safety is “a compelling interest at the heart of government’s function”).

206. 21 C.F.R. § 808.35(b) (2019).

207. *Id.* § 808.35(b)(6).

208. *Cf. Whitman v. Am. Trucking*, 531 U.S. 457, 466 (2001) (holding that absent express authorization, agencies may not consider cost in determining if a proposed regulation advances the public health).

209. *Our Mission and What We Do*, EPA (Feb. 7, 2018), <https://www.epa.gov/aboutepa/our-mission-and-what-we-do> (noting that the EPA works to ensure that federal laws protecting the environment are administered and enforced fairly).

210. See discussion *supra* Section I part D(i).

The EPA already has a long and successful history of risk-risk balancing, like the considerations at issue here between environmental, health, and safety concerns. For example, the Safe Drinking Water Act requires the EPA to set standards for chemical contaminants in drinking water. The EPA first sets a goal at “the level at which no known or anticipated adverse effects on the health of persons occur,”<sup>211</sup> then sets an enforceable limit at the level “as close to the maximum contaminant level goal as is feasible.”<sup>212</sup> However, the enforceable level may be altered if needed to ensure the best overall drinking water quality—such as if treating a given contaminant will create more contaminants or interfere with other steps in water treatment.<sup>213</sup> The chlorine that is used to kill microorganisms in drinking water does leave behind carcinogenic by-products.<sup>214</sup> However, the reduction in mortality from waterborne diseases associated with chlorinating water vastly outweighs this risk, so the United States continues to chlorinate our drinking water—and we are overall much healthier for it.<sup>215</sup>

Granting the EPA a general power of preemption in regulating ETO (and other harmful but seemingly necessary chemicals), coupled with a freely-granted waiver option, would enable protection of the public health with minimal disruption of state autonomy. States would generally remain free to act however they think best. However, state action would be subject to federal oversight that could intervene if—but only if—state action caused a direct threat to the health of the nation.<sup>216</sup>

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211. 42 U.S.C. § 300g-1(b)(4)(A) (2018).

212. *Id.* § 300g-1(b)(4)(B).

213. *Id.* § 300g-1(b)(5)(A).

214. Ahmed Mahmoud El-Tawil, *Colorectal Cancers and Chlorinated Water*, 8 *WORLD J. GASTROINTESTINAL ONCOLOGY* 402 (2016).

215. AM. WATER WORKS ASS'N, *WATER CHLORINATION/CHLORAMINATION PRACTICES AND PRINCIPLES* 2–6 (2d ed. 2006).

216. It is also important to distinguish a number of conclusions that this Note does not draw. First, this Note does not discuss whether the law should be changed, and federal regulatory power enlarged, because state law actions may make sterilizing medical devices more expensive. These kinds of local cost/benefit calculations are exactly why federal statutes such as the CAA allow states to enact their own rules, a topic which has been thoroughly debated elsewhere. Rather, the concern addressed here is the direct health impact that a shortage of sterile products would cause. Second, this Note does not suggest what the outcome of further study of ETO sterilization would be. It is entirely plausible that the harm to workers and communities from the release of ETO

E. COMPREHENSIVE STATUTORY REFORM IS A BETTER SOLUTION THAN OFFSHORING THE PRODUCTION OF STERILIZED MEDICAL DEVICES

Enormous amounts of medical manufacturing is already done overseas. India currently supplies approximately half of the world's vaccines, and produces around forty percent of all generic drugs consumed in the U.S.<sup>217</sup> China meanwhile produces around thirty percent of the U.S. market for medical devices<sup>218</sup> and ninety-seven percent of the antibiotics used in the U.S.<sup>219</sup> All told, approximately eighty percent of all active pharmaceutical ingredients used in the U.S. are manufactured abroad.<sup>220</sup> Given these existing trends within the medical manufacturing industry, it seems likely that if the United States cannot adequately address how companies can continue to sterilize medical devices domestically, the result will be that these functions will be sent offshore. However, exporting these capabilities in order to avoid U.S. environmental laws raises serious issues in regard to both ethics and the stability of the U.S. public health supply chain.

Simply offshoring the capabilities to countries with less strict environmental regulation raises profound concerns of environmental justice.<sup>221</sup> If we think ETO is too dangerous to

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could outweigh the benefits of its use to consumers of sterilized goods. A potential device shortage could, in theory, adversely affect the health of fewer people than the continued operation of ETO sterilization facilities. The problem is not that some analysis has found the use of ETO to be unjustified. The problem is that, under the current legal structure, no regulator is doing this analysis.

217. Charlotte Edwards, *Pharmaceutical Manufacturing Companies in India: Ones to Watch*, PHARMACEUTICAL TECH. (Aug. 6, 2018), <https://www.pharmaceutical-technology.com/features/pharmaceutical-manufacturing-companies-in-india/>.

218. Mihir Torsekar, *Pain in the (Supply) Chain: Tariffs and U.S.-China Medtech Trade*, MED. PRODUCTS OUTSOURCING (Apr. 3, 2019), [https://www.mpo-mag.com/issues/2019-04-01/view\\_columns/pain-in-the-supply-chain-tariffs-and-us-china-medtech-trade/](https://www.mpo-mag.com/issues/2019-04-01/view_columns/pain-in-the-supply-chain-tariffs-and-us-china-medtech-trade/).

219. Yanzhong Huang, *U.S. Dependence on Pharmaceutical Products from China*, COUNCIL ON FOREIGN REL. (Aug. 14, 2019), <https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china>.

220. *Id.*

221. "Environmental Justice" has been described as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies." *Environmental Justice*, EPA, <https://www.epa.gov/environmentaljustice> (last visited Mar. 8, 2020).

work within our communities, why would it be better to ship it off to have someone else, in a poorer and less-developed nation, do the same work? Environmental justice advocates have long raised arguments that the placement of heavily polluting facilities within poorer communities, often disproportionately populated by people of color, constitutes “environmental racism.”<sup>222</sup> Especially given the relative ease with which ETO emissions can be controlled,<sup>223</sup> it may be that the most ethical course of action would be to ensure that sterilization facilities are kept in the U.S., where they can be subject to more thorough oversight.

The globalization of the medical supply chain can also have the unintended consequence of making the public health more vulnerable to disruptive events. The recent coronavirus outbreak has shown that public health emergencies can leave countries without their own production facilities in extremely precarious situations. As COVID-19 spreads, many countries, including China and India, have limited or banned the export of certain medical products.<sup>224</sup> Such bans threaten to create further shortages—including shortages of products not directly related to the emergency, such as the common painkiller paracetamol.<sup>225</sup> Future disruptions could come from any range of natural disasters. An earthquake or wildfire is tragedy enough when it occurs; concentrating such a vital industry as medical manufacturing in fewer places by offshoring much of the capability invites secondary tragedies as people perhaps thousands of miles from the initial disaster are left without

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222. Renee Skelton & Vernice Miller, *The Environmental Justice Movement*, NRDC (Mar. 17, 2016), <https://www.nrdc.org/stories/environmental-justice-movement>.

223. CR CLEAN AIR GROUP, *supra* note 31.

224. See, e.g., Hannah Ellis-Petersen, *India Limits Medicine Exports After Supplies Hit by Coronavirus*, GUARDIAN (Mar. 4, 2020), <https://www.theguardian.com/world/2020/mar/04/india-limits-medicine-exports-coronavirus-paracetamol-antibiotics> (India); Angela Oketch, *Coronavirus: China Drugs Export Ban Sees Costs Shoot Up*, DAILY NATION (Mar. 5, 2020), <https://www.nation.co.ke/news/Coronavirus—China-drugs-export-ban-sees-costs-shoot-up/1056-5478720-14kxl64/index.html> (China); Associated Press, *EU Seeks United Front to Tackle Medical Shortages from Virus*, N.Y. TIMES (Mar. 6, 2020), <https://www.nytimes.com/aponline/2020/03/06/world/europe/ap-eu-virus-outbreak-europe.html> (Germany, Czech Republic).

225. *Coronavirus: Drug Shortage Fears as India Limits Exports*, BBC NEWS (Mar. 4, 2020), <https://www.bbc.com/news/business-51731719>.

necessary medical products. It will therefore be advantageous for the U.S. to develop a long-term solution to the problem, that increases the odds of sterilization continuing domestically.

### CONCLUSION

While undertaken in an attempt to protect the local population from harm, a number of state actions tightening regulations on ETO could end up having exactly the opposite effect. ETO is the most commonly used chemical for sterilizing medical devices—and currently has no viable replacement.<sup>226</sup> A sudden ban of the use of ETO could cause dangerous shortages of necessary healthcare materials. Rather than protect the public, the states' knee-jerk reaction banning the use of ETO could end up costing lives. Because of the balkanization of federal regulatory power, no single agency can consider both the environmental costs and the healthcare needs associated with ETO use. This leaves the federal government without any formal abilities to prevent this potential crisis.

In order to prevent state actions from damaging the supply of life-saving medical devices, environmental statutes including the CAA should be amended to more strongly preempt state actions. Concurrently, states should be given the ability to apply for a waiver of that preemption, which should be freely granted unless the state action threatens the public health. Federal regulation bypasses a number of issues associated with local control.<sup>227</sup> A system where states apply for preemption waivers that are freely given, but may be retracted, provides a balance of state and federal interests. States' powers to set local policy will remain generally undisturbed, yet federal oversight will prevent a multitude of local self-interests from creating a national crisis.

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226. See Sharpless, *supra* note 14.

227. See *supra* Section II.C.