**STATE OF NEW MEXICO**
**COUNTY OF DOÑA ANA**
**THIRD JUDICIAL DISTRICT COURT**

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| **THE STATE OF NEW MEXICO, ex rel. HECTOR BALDERAS, ATTORNEY GENERAL**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**STERIGENICS U.S. LLC, SOTERA HEALTH HOLDINGS, LLC, SOTERA HEALTH LLC, AND SOTERA HEALTH COMPANY**<br><br>**Defendants** | No: D-307-CV-2020-02629<br>Beyer, Marci |

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# *AMICI CURIAE* BRIEF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED), THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND THE NEW MEXICO CHAMBER OF COMMERCE

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Dalva L. Moellenberg
Gallagher & Kennedy, P.A.
1239 Paseo de Peralta
Santa Fe, New Mexico 87501
505-982-9523
DLM@gknet.com

Douglas A. Henderson*
King & Spalding LLP
1180 Peachtree Street
Atlanta, Georgia
404-572-2769
dhenderson@kslaw.com
**Pro Hac Application Pending*

***Attorneys for Amici Curiae***

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## INTEREST OF AMICI CURIAE

*Amici curiae* submit this brief in accordance with this Court's Order dated April 22, 2021, requesting amicus participation from organizations interested in this matter

*Amici curiae* include the Advanced Medical Technology Association ("AdvaMed"), the Chamber of Commerce of the United States of America ("U.S. Chamber of Commerce" or "U.S. Chamber"), the National Association of Manufacturers ("NAM"), and the New Mexico Chamber of Commerce ("New Mexico Chamber"). These organizations include members that manufacture, research, produce, and sell medical devices regulated by the Food & Drug Administration ("FDA"), emit substances regulated by the U.S. Environmental Protection Agency ("EPA") under the Clean Air Act, and monitor their workers under regulations developed and enforced by the Occupational Safety and Health Administration ("OSHA"). *Amici* have a substantial interest in the regulatory requirements associated with the sterilization of medical products and the laws and regulations that govern manufacturing facilities in the United States. Their members, as well as the consuming public, will be adversely impacted if tort litigation can be used to interfere with the comprehensive and safe regulation of medical device facilities by federal and state regulators.

**AdvaMed** is the world's largest medical technology association, with approximately 400 member companies that develop medical devices, diagnostic tools, and health information systems. Its members span every field of medical science and range from cutting-edge startups to multinational manufacturers, all dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards. The innovations created by AdvaMed's members advance efficiency in health care through earlier disease detection and more effective treatments which, in turn, reduce the economic burden of disease and allow people to live longer, healthier, and more productive lives.

The **U.S. Chamber of Commerce** is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the U.S. Chamber regularly files *amicus* curiae briefs in cases, like this one, that raise issues of concern to the nation's business community.

The **NAM** is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The **New Mexico Chamber of Commerce** is the statewide chamber of commerce and has represented every industry and in every region of the state for over sixty years. The New Mexico Chamber's mission is to be the driving force that unites the business community to make New Mexico a leader in industry, innovation, economic competitiveness and overall quality of life. The New Mexico Chamber's membership includes manufacturers who rely upon clear and reasonable laws and regulations governing health and safety in conducting complex operations as well as medical providers who rely upon medical devices and supplies that meet FDA and other standards for use in meeting the health needs of New Mexicans.

For *Amici*, the certainty and consistency of national environmental standards is essential to providing a reliable supply of critical medical products sterilized with ethylene oxide ("EO"), the substance used to sterilize most medical products in the United States. At issue in this case is the appropriate role of scientific agencies in developing new and enforcing existing regulatory requirements. If accepted, the Attorney General's claims in this case will create a potential duplicative, or parallel, environmental enforcement framework that will unnecessarily confuse environmental compliance for medical product manufacturers, and indeed for other manufacturers and regulated parties, with implications across the United States. If new emission standards and best practices are developed by trial courts and juries in public nuisance lawsuits, *Amici'* members would be significantly affected due to the inconsistent and unpredictable standards that would govern their conduct. *Amici*'s members require certainty and stability to make their investment and compliance decisions, and they rely heavily on the determinations made by expert agencies under complex statutory and regulatory frameworks such as the Clean Air Act framework. Accordingly, *Amici* have a substantial interest in ensuring deference is accorded to the U.S. Environmental Protection Agency's ("EPA") and the New Mexico Environmental Department's ("NMED") responsibility for regulating and enforcing the use, management, and emissions of EO at the Santa Teresa Plant. [1]

[1] *Amici* state that no counsel for a party authored this brief in whole or in part and that no person other than *amici*, their members, and their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

## INTRODUCTION AND SUMMARY OF ARGUMENT

Under the federal Clean Air Act, Congress granted the U.S. Environmental Protection Agency ("EPA") authority to develop regulations that protect human health and the environment for substances such as ethylene oxide ("EO"), a "hazardous air pollutant" under the Clean Air Act, used to sterilize most medical products in the United States today. Exercising that authority, EPA acted deliberately and carefully to develop regulations, set emission standards, define effective air quality control technologies, and issue agency guidance relating to the use and emission of EO. EPA, in ensuring state regulators play an important role in federal environmental law enforcement, delegated responsibility for administering and enforcing the Clean Air Act EO regulations to the New Mexico Environmental Department ("NMED"), the agency the Legislature created to be the "single" environmental agency for New Mexico.

In implementing this federal-state framework, Congress and the New Mexico Legislature recognized that specialized agencies, such as EPA and NMED, are best suited to set technical and industry-specific standards and enforce environmental laws because they employ subject matter experts and rely on industry knowledge to weigh the costs and benefits of new environmental requirements as appropriate. Both Congress and the New Mexico Legislature created carefully balanced processes under which EPA and NMED create and enforce environmental standards and regulations. These processes involve notice-and-comment rulemaking, or in the case of New Mexico, the Environmental Improvement Board hearing process, to set standards and issue permits that adequately protect the public while balancing the benefits and costs of regulation.

In filing its present request for injunctive relief, the Attorney General asks this Court to supplant the rulemaking and decision-making authority of no fewer than four federal and state administrative bodies specifically empowered to regulate the medical device industry and EO

sterilization activities as a whole: EPA, NMED, OSHA, and FDA. By seeking the requested injunctive relief, the Attorney General seeks to side-step the expertise and regulations of each of those agencies and, instead, impose a standard-less, novel public nuisance theory that, in essence, seeks to regulate EO by forcing this Court into the role of regulator that will not only jeopardize access to critical medical products in the midst of a global pandemic, but also disrupt manufacturing and sterilization activities in this State.

Because few areas are as technically and scientifically challenging as the sterilization of regulated medical products with EO, specialized agencies are best suited to determine the central questions in this lawsuit: (1) whether a zero EO emissions standard for certain practices at commercial sterilizers conflicts with the goals and requirements of the Clean Air Act, (2) whether additional EO emission controls and management practices on garage and truck doors are warranted to protect human health and the environment, and (3) whether the costs and benefits of plant-specific EO-emission requirements are reasonable and appropriate, considering the potential adverse effects on the supply of safe medical products sterilized with EO. Should any party object to the expert agencies' determinations concerning these questions, there are well established mechanisms for seeking judicial review of such administrative determinations.

*Amici* respectfully submit this Court should apply controlling New Mexico case law regarding the doctrine of primary jurisdiction and defer to the rulemaking and enforcement authority of EPA and NMED. Dismissing or staying this case would advance the central rationale for the doctrine of primary jurisdiction—employing the specialized knowledge of agencies and promoting uniformity in the use, management, and emission of EO, a substance critical to ensuring the supply of safe medical products integral to healthcare workers and patients.[2]

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[2] See *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 673 (2003) (Breyer, J., concurring) (discussing purpose of primary jurisdiction doctrine).

## I. THE INJUNCTIVE RELIEF SOUGHT BY THE ATTORNEY GENERAL WOULD DIRECTLY CONFLICT WITH EXISTING EPA AND OSHA REGULATIONS AND REWRITE EXEMPTIONS AND THRESHOLDS UNDER FEDERAL AND STATE ENVIRONMENTAL LAWS, WITHOUT ANY ADEQUATE EXPLANATION FOR DOING SO.

The Attorney General invokes a novel public nuisance theory in attempting to impose its own EO emission requirements on the Santa Teresa Plant at issue in this case. The sought-after relief is nothing less than *de facto* environmental regulation. For instance, the Attorney General requests not only that Sterigenics "immediately cease *any and all* uncontrolled emissions or releases of [EO] from the Santa Teresa Plant …" but also that it stop "causing, making, facilitating or *otherwise allowing any uncontrolled emission or release* of [EO] from the Santa Teresa Plant …."[3] Even more specifically, the Attorney General demands that Sterigenics stop "leaving sterilization chamber, aeration room doors, and other interior doors open when not in use," "allowing 'off-gassing' associated with the storing, transporting, or handling of EtO prior to charging of sterilization chambers," "allowing the 'off-gassing' of EtO from 'under-controlled' aeration rooms …" and allowing EO to "escape through pipes, equipment, vents, stacks, or other point sources prior to filtration or processing through fully functioning emission controls."[4]

If required by the Court, the actions requested by the Attorney General would create new requirements for EO emissions and transportation (i.e., "zero" releases), new schedules for EO compliance (i.e., "immediately" comply), and unspecified, but new EO process procedures on the Santa Teresa Plant (i.e., address "under-controlled" sources). Imposing those new requirements, schedules, and processes would require this Court to second guess the expert judgments of EPA in regulating air quality, OSHA in regulating workplace safety, and the FDA in ensuring that

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[3] Complaint, Prayer for Relief, ¶C (emphasis added).

[4] Complaint, Prayer for Relief, ¶C (emphasis added). See also Emergency Motion (April 14, 2021), Attached Proposed Temporary Restraining Order.

healthcare workers and patients have access to safe medical devices. The Attorney General provides no explanation for replacing these judgments with his own and provides no suggested standards for a court to determine what level of additional EO control is appropriate.

### A. The Attorney General's Requested Relief Would Impermissibly Interfere with EPA's Regulations of the Use, Management, and Emissions of Ethylene Oxide under Subpart O of the Clean Air Act.

Each of the Attorney General's requests for injunctive relief implicate and, in many instances, contradict existing EO federal and state regulations. Implicit in the Attorney General's request is a central mistaken premise: that EO emissions are never allowed by the Clean Air Act or other laws unless they are "controlled." However, as explained below, certain EO emissions, although regulated under the Clean Air Act, are not subject to control requirements. In fact, EPA's regulations include specific requirements defining which EO emissions are and are not permitted. These specific requirements reflect the difficult policy and technical judgments that specialized agencies make when regulating emissions, including through notice and comment rulemaking.

In 1994, when it undertook regulation of EO, EPA considered a wide range of issues, including not only the health effects of EO, but also the available EO-control technologies and benefits of sterilized medical products to health care.[5] Under the Clean Air Act, when EPA promulgates such regulations, it sets standards taking into account the costs of achieving emission reductions and considering non-air quality health and environmental impacts and energy requirements.[6]

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[5] 59 Fed. Reg. 62,585 (Dec. 6, 1994).

[6] *See Cal. Communities Against Toxics v. Pruitt*, 241 F. Supp. 3d 199, 201 (D.D.C. 2017) (in setting initial standards for hazardous air pollutants, "EPA establishes emission floors for each pollutant and source category, and then the agency sets stricter but 'achievable' standards—taking into account 'the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements'" (citing 42 U.S.C. § 7412(d)(2)); *id*. (in periodically reviewing and, if necessary, revising such standards, EPA is required to "determine whether any changes [are] necessary to 'provide an ample margin of safety to protect public health' or to 'prevent ... an adverse environmental effect,' subject to considerations like cost . . ." (citing 40 C.F.R. § 7412(f)(2)(A))); *see also Sierra Club*

Based on that assessment, when EPA promulgated regulations implementing "Subpart O" of the Clean Air Act to regulate EO usage at medical product sterilizers,[7] the agency carefully defined "aeration room," "aeration room vent," "chamber exhaust vent," "deviation," "manifolding emissions," "sterilization chamber," "sterilization chamber vent," and "sterilization facility."[8] With respect to this case, the Attorney General continues to invoke his own interpretation of EO emissions from "sterilization chambers" and "aeration room," key technical terms defined and regulated by EPA and NMED, that, if a preliminary injunction is granted, could be interpreted without involving EPA or NMED.

In the Subpart O regulations, EPA also determined that facilities using less than 2,000 pounds of EO per year were exempt from Subpart O control technology and EO emission standards.[9] EPA similarly exempted EO sterilization operations at hospitals, doctor offices, clinics, or other facilities providing medical services from Subpart O's requirements.[10] Subpart O also includes numerous reporting and recordkeeping requirements that EPA enforces.[11] Accordingly, EPA regulates and does not bar all "uncontrolled" EO emissions.

The Subpart O regulations are based on Section 112 of the Clean Air Act, which requires EPA to set National Emission Standards for Hazardous Air Pollutants ("NESHAP") emission control standards for "hazardous air pollutants," including EO.[12] Section 112 requires existing

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*v. EPA*, 167 F.3d 658, 666 (D.C. Cir. 1999) and *Sierra Club v. EPA*, 353 F.3d 976, 989 (D.C. Cir. 2004) (holding EPA cannot set emission standards for hazardous air pollutants based on specific control measures unless there is "evidence in the record about the costs of the pollution prevention measures").

7 40 C.F.R. § 63.360 et seq., available at: https://www.govinfo.gov/content/pkg/CFR-2015-title40-vol10/pdf/CFR-2015-title40-vol10-part63-subpartO.pdf

8 40 C.F.R. § 63.361.

9 40 C.F.R. § 63.360(b) (sterilization sources using less than 1 ton of EO are not subject to the emission standards in §63.362, but the recordkeeping requirements in § 63.367(c) apply). In addition, the EO emissions at the Santa Teresa Plant fall below the NMED thresholds for emissions. 20.2.72.219B(1)(f) NMAC.

10 40 C.F.R. § 63.360(e).

11 40 C.F.R. § 63.364 (monitoring); §63.366 (reporting); §63.367 (recordkeeping).

12 42 U.S.C. § 7412(d); *id*. § 7412(b)(1) (initial list of hazardous air pollutants expressly includes EO).

and new *major* sources[13] to control emissions to the level achievable by the maximum achievable control technology ("MACT").[14] Section 112 also requires smaller *area*[15] sources to control emissions, often using generally available control technology or management practices ("GACT").[16]

Applying the MACT standard for "hazardous air pollutants," EPA imposed strict EO "destruction" standards and strict EO emission standards. Specifically, Subpart O requires sterilizers using more than 2,000 lbs/yr of EO (such as the Santa Teresa Plant) to reduce EO emissions to the atmosphere from a "source subject" to a "maximum concentration of 1 ppmv [parts per million volume] or at least 99 percent, whichever is less stringent."[17] When it developed these regulations, EPA considered "storage and loading losses" during its EO rulemaking process and chose not to apply controls for those conditions.[18] For non-"source" EO facilities, or for EO area facilities, EPA imposes less stringent EO emission standards and controls.

Contrary to the Attorney General's suggestion, EPA has determined that the release of certain amounts and certain concentrations of EO *is* acceptable under the Clean Air Act because it

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[13] The term "major source" ordinarily refers to a stationary source that "emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants." *Id*. § 7412(a)(1). However, EPA may establish a lesser quantity "on the basis of the potency of the air pollutant, persistence, potential for bioaccumulation, other characteristics of the air pollutant, or other relevant factors." *Id*.

[14] The MACT standard is "maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing sources in the category or subcategory to which such emission standard applies, through application of measures, processes, methods, systems or techniques." 42 U.S.C. § 7412(d)(2).

[15] "Area source" means any stationary source of hazardous air pollutants "that is not a major source." 42 U.S.C. § 7412(a)(2).

[16] 42 U.S.C. § 7412(d)(2); https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities.

[17] 40 C.F.R. § 63.362(a) (Table 1).

[18] EPA, Locating and Estimating Air Emissions from Sources of Ethylene Oxide. EPA-450/4-84-007L, at 48 (Sept. 1986) (EO emission sources at sterilization facilities other than direct emissions are assumed to be negligible). https://www.epa.gov/sites/production/files/2020-11/documents/ethylene_oxide.pdf

would not create adverse human health or environmental effects. With respect to the allegations in this case, EPA *allows* facilities to release EO remaining after treatment with air quality control technologies exhibiting a 99% destruction efficiency or EO concentrations equal to or less than a 1 ppmv standard. From a different perspective relevant to this case, the 1% of EO that is not destructed is permitted by EPA Subpart O regulations to be released into the atmosphere. EPA's determination was based on consideration of evidence and judgments developed by its toxicological experts, air quality engineers, and industry specialists across a wide range of companies producing critical medical devices regulated by the FDA.[19]

In its initial 1994 EO rulemaking, EPA addressed EO emissions from "ethylene oxide storage areas," such as the unloading dock doors emphasized by the Attorney General.[20] Addressing this category of emissions, EPA concluded that "OSHA requirements limiting worker exposure to a maximum of 1 ppmv ethylene oxide should be sufficient to limit these fugitive emissions points and protect employees."[21]

The Attorney General mistakenly assumes that all EO releases are "uncontrolled" releases. But as a matter of law, if certain EO-emissions are exempted from Subpart O requirements by EPA, those emissions should not be characterized as "uncontrolled" or "under-controlled."

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19 *See, e.g.,* 71 Fed. Reg. 17,712 (Apr. 7, 2006) (finalizing EPA's decision not to revise the Ethylene Oxide Emission Standards for Sterilization Facilities, after concluding revisions were not necessary "to protect public health with an ample margin of safety and to prevent adverse environmental effects"; after conducting "risk and technology reviews," EPA concluded "no additional control requirements are warranted"), *at* https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities; Memorandum from ICF Consulting to EPA (July 27, 2004) (setting forth data and assumptions used for the screening-level residual risk analysis of the commercial ethylene oxide sterilizers and fumigators source category) *at* https://www.regulations.gov/document/EPA-HQ-OAR-2003-0197-0003; EPA, Residual Risk Assessment for the Ethylene Oxide Commercial Sterilization Source Category (Sept. 23, 2005) (describing the methods and results of the residual risk assessment for the ethylene oxide (EO) commercial sterilization source category) *at* https://www.regulations.gov/document/EPA-HQ-OAR-2003-0197-0013.

20 EPA, Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations - Background Information for Final Standards: Summary of Public Comments and Responses, EPA-453/R-94-084b (Nov. 1994) ("1994 EPA Responses to Comments") at 2-5.

21 1994 EPA Responses to Comments at 2-6.

Accordingly, when the Attorney General suggests additional EO "controls" are needed at the Santa Teresa Plant, he is asking this Court to sidestep the prescribed administrative process created by Congress and EPA, which elicits the judgment of expert federal regulators and participation of all interested parties, and apply a standard other than the federal MACT standard and GACT standards. By advocating for a "zero" discharge standard threshold for "uncontrolled EO-emission" from garage doors, loading and unloading trailers, and other activities, the Attorney General effectively seeks to rewrite critical definitions in Subpart O, crafting a new category of "other" sterilization facilities emissions. If an injunction were issued to stop "any" EO emissions, the Santa Teresa Plant would become subject to an EO-threshold that exists nowhere else in the United States and that was never assessed or developed by any specialized regulatory agency. While the use of "any" rewrites how EO is regulated under the Clean Air Act, the Attorney General does so without providing explanation and without articulating any standards by which this court could determine what level of regulation is needed or appropriate for new or existing facilities.

If this Court were to issue an injunction to implement a zero EO emission standard for these activities—a standard far more stringent than the EPA or NMED Subpart O requirements—commercial sterilizers, such as the Santa Teresa Plant, would be forced to install new control technologies, retrofit existing facility structures, redesign medical product packaging, construct new warehouses with zero emissions systems, and perhaps stop operations, all without any showing of the technical feasibility of the new court-crafted standards and without having any prior notice of the newly created EO standards. Even more challenging, no sterilizer would ever know what technologies would be acceptable to meet this new zero "under-controlled" EO standard announced by the Attorney General.

### B. The Attorney General's Requested Injunctive Relief Would Implicate and Effectively Interfere with OSHA's Worker Exposure Standard for EO.

The same potential for regulatory conflict and confusion arises when one attempts to harmonize the Attorney General's requested relief with the OSHA EO worker standard. Under OSHA's EO-standard, issued under the Occupational Safety and Health Act of 1970, Sterigenics is required to monitor employees to ensure they are not exposed to EO concentrations above the "OSHA permissible exposure levels." Whether an employee is working in the sterilizer, warehouse, or garage, OSHA requires EO testing to ensure that the ambient air workspace concentrations are safe using the ambient air concentrations developed by OSHA.

Like EPA, OSHA also has promulgated very detailed regulations addressing EO air quality concentrations at commercial sterilizers.[22] The starting point in any screen for EO exposure concerns is the OSHA "action level" for EO equal to a concentration of airborne EO of 0.5 parts per million (ppm).[23] In addition, OSHA developed a "permissible exposure limit" for EO is 1 ppm based on an 8- hour time weighted average exposure that applies across the United States.[24] An OSHA permissible exposure level is the agency's most stringent standard for determining EO-exposure hazards. OSHA also has also developed an "excursion limit" for EO: an "employer shall ensure that no employee is exposed to an airborne concentration of EO in excess of 5 parts of EO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes.[25]

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22 29 C.F.R. §1910.1047.

23 29 C.F.R. §1910.1047(b).

24 29 C.F.R. §1910.1047(c).

25 29 C.F.R. §1910.1047(c)(2). OSHA also has regulations covering a wide range of EO issues, including initial monitoring, monitoring frequency, termination of monitoring, accuracy of monitoring, employee notification, regulated areas, engineering controls and work practices, respirator selection, emergency response, medical surveillance, medical examinations, communication of hazards, signs and labeling, employee training, record keeping. By law, Sterigenics is required to comply with these EO monitoring requirements at the Santa Teresa plant. 29 C.F.R. §1910.1047(d).

The dilemma for medical product sterilizers is self-evident. If this Court were to grant the injunctive relief requested by the Attorney General, medical product sterilizers would be required to control EO in these areas at concentrations less than the OSHA permissible exposure level for EO. Because the Attorney General never ties his "uncontrolled" theory of EO-releases to any OSHA ambient air standard or heath standards, his requested relief by implication would effectively *lower* OSHA's "permissible exposure level" for sterilizers, increasing EO requirements at the Santa Teresa Plant. The Attorney General's requested injunctive relief would raise precisely the technical air quality issues that Congress intended EPA and OSHA to decide. Again, the Attorney General provides no explanation for his proposed zero-emissions requirement and offers no standards by which a court could assess whether a particular level of emissions is appropriate.

### C. The Attorney General's Requested Relief Incorrectly Assumes Exposure to any Regulated Substance at any Concentration is an "Injury" Requiring Medical Monitoring.

The Attorney General suggests that mere exposure to EO equates to an injury on the theory any increased risk (without any discussion of the actual EO risks based on actual testing) constitutes an injury under applicable laws. According to the Attorney General, because "Defendants' conduct has significantly increased thousands of New Mexico residents' risk of serious adverse health effects, Defendants must fund a public health monitoring program designed to detect, assess, and treat medical disorders associated with EtO exposure, under State supervision."[26] But the Attorney General cites no case law supporting his position. In fact, there are no cases in his favor under New Mexico law.[27]

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[26] Complaint, ¶142.

[27] See D. Scott Aberson, *A Fifty-State Survey of Medical Monitoring and the Approach the Minnesota Supreme Court Shout Take When Confronted with the Issue*, 32 Wm. Mitchell L. Rev. 1095, 1116 (2006) (no New Mexico medical monitoring law)

In considering the Attorney General's position, the Court should look to a recent order from a state district court in Colorado for guidance. In *Smith v. Terumo BCT*, the district court judge held that EO exposures do not constitute an "injury" requiring "medical monitoring," rejecting that plaintiff's theory that increased EO risk constituted a nuisance.[28] In reaching this conclusion, the judge reviewed cases around the country and rejected plaintiffs' reliance on the same National Air Toxics Assessment upon which the Attorney General relies here. While the district court applied Colorado law, the point is clear—absent a whole range of proof issues, the release of EO described by the Attorney General does not equate to a tort requiring medical monitoring. If that were the case, ordinary activities that emit EO, from burning charcoal to making kimchi, would be a "public nuisance" requiring medical monitoring, which cannot be the law.

## II. UNDER THE PRIMARY JURISDICTION DOCTRINE, NEW MEXICO COURTS REGULARLY DISMISS OR STAY PUBLIC NUISANCE SUITS INVOLVING COMPLEX ENVIRONMENTAL REGULATIONS, FINDING EPA AND NMED ARE BEST SUITED TO REGULATE AND ENFORCE TECHNICAL AIR QUALITY EMISSIONS ISSUES

This case presents a textbook example of a situation where the doctrine of primary jurisdiction should apply given the significant number of expert administrative agencies tasked with regulating EO use and emissions.[29]

### A. This Case Should be Dismissed or Stayed Under *Norvell*, an Air Quality "Public Nuisance" Case that is Indistinguishable from this Case.

The seminal New Mexico case applying the primary jurisdiction doctrine involved an attempt by the Attorney General to regulate emissions as a "public nuisance" without involving

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[28] Order: Defendants' Motion to Dismiss, Smith v. Terumo BCT et al., No. 2019CV031822 (Dist. Ct. Jefferson, Feb. 16, 2021). A copy of this Order is attached as Exhibit A.

[29] Courts regularly dismiss public nuisance cases on primary jurisdiction grounds where the subject matter requires interpretation of complex regulations by EPA or similar expert agencies. See *Rural Cmt. Workers All v. Smithfield Foods, Inc.*, 459 F. Supp. 3d 1228, 1240-41 (W.D. Mo. 2020) (deferring to OSHA under primary jurisdiction and

the predecessor to NMED. In *State Ex Rel. Norvell v. Arizona Public Service Co.*, the State sought injunctive relief to abate a series of alleged public nuisances caused by gas and water emissions originating from a New Mexico power plant.[30] The Supreme Court of New Mexico noted:

> The doctrine of primary jurisdiction . . . is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties . . . . "Primary jurisdiction" . . . applies where the claim is originally cognizable in the courts, and comes into play whenever enforcement of a claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views.[31]

Recognizing that air quality poses "a complex social, economic, and technological problem,"[32] the Court established a presumption in favor of agency enforcement of issues relating to human health and the environment. As the Court explained, "**[t]he legislature has created the agency in order to afford a systematic method of factfinding . . . and the agency's jurisdiction should be given priority in the absence of a valid reason for judicial intervention.**"[33] The presumption, therefore, is that NMED should be the factfinder for technical environmental matters.

*Norvell* is directly on point. As in *Norvell*, the Attorney General is attempting here to regulate air emissions as a public nuisance without providing a persuasive rationale for judicial intervention that would overcome the ordinary presumption in favor of deferring to agency jurisdiction. As in *Norvell*, administrative agencies—including, EPA and NMED—have been

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dismissing public nuisance claims); *Kerr-McGee Chem. Corp. v. Dep't of Nuclear Safety*, 204 Ill. App. 3d 605, 611 (1990) (invoking primary jurisdiction to defer to agency); *B.H. v Gold Fields Mining Corp*., 506 F. Supp. 2d 792, 805 (N.D. Okla. 2007) (deferring to "EPA's expertise" under primary jurisdiction); *Jones v. Halliburton Energy Servs., Inc*., No. CIV-11-1322-M, 2016 WL 1212133, *3 (W.D. Okla., Mar. 25, 2016) (dismissing nuisance claim where state environmental agency was investigating site); *Collins v. Olin Corp*., 418 F. Supp. 2d 34 (D. Conn. 2006) (dismissing nuisance claim for injunctive relief where state environmental agency was overseeing issues).

30 *State Ex Rel. Norvell v. Ariz. Pub. Serv. Co.*, 1973-NMSC-051, 85 N.M. 165.

31 *Id. at 171 (citing United States v. Western Pacific Railroad Co.*, 352 U.S. 59, 77 (1956)). Other courts express similar views. *See Ellis v. Tribune Television Co*., 443 F. 3d 71, 81 (2d Cir. 2006) (central purpose of primary jurisdiction is to ensure that courts and agencies do not work at cross purposes).

32 *Id*. at 169 (internal citations omitted).

33 *Id.* at 171 (emphasis added).

delegated authority to promulgate and enforce regulations and facility-specific permits pursuant to active and comprehensive regulatory programs involving multiple complex considerations and requiring the exercise of specialized scientific and technical expertise. And as in *Norvell*, the agencies' primary jurisdiction should be given priority.

*Norvell* applies especially when EPA is currently in the process of reassessing the EO regulations, including EO emissions related to vents, off-gassing, and opening and closing doors, as alleged by the Attorney General. Indeed, this very argument was directly addressed and dismissed in *Norvell*. In *Norvell*, plaintiffs argued that primary jurisdiction should not apply because the relevant state agency had not, at the time of litigation, adopted mercury emissions standards.[34] The New Mexico Supreme Court rejected the argument, explaining that, even though the agency had not yet adopted standards, it was sufficient for purposes of primary jurisdiction that the agency was "studying the problem with a view to adopting such regulations."[35]

### B. Under the *Schwartzman* Primary Jurisdiction Factors Developed by the U.S. District Court for New Mexico, this Case Should be Dismissed or Stayed.

The U.S. District Court for District of New Mexico, in *Schwartzman, Inc. v. Atchison Topeka & Santa Fe Ry. Co*.,[36] applied five factors to dismiss a public nuisance claim where EPA and NMED had authority to address the underlying issues: (1) whether the court "is being called upon to decide factual issues which are not within the conventional experience of judges . . . "; (2) "whether defendant could be subjected to conflicting orders of both the Court and the administrative agency. . . "; (3) "whether relevant agency proceedings have actually been initiated . . . "; (4) "whether the agency has demonstrated diligence in resolving the issue or has instead

34 *Id.* at 172.
35 *Id.*
36 857 F. Supp. 838 (D.N.M. 1994).

allowed the issue to languish . . . "; and (5) "the type of relief requested."[37] Each of the *Schwartzman* factors weighs in favor of dismissing this case under the doctrine of primary jurisdiction.

As for the first, second, and fifth factors, the trial court and juries will be asked in this case to decide fundamental issues not within the expertise of judges or a lay jury. Two examples prove the point. Early on in this case, the court will have to interpret the "inhalation unit risk" factor for EO developed by EPA and assess the purpose of the National Air Toxics Assessment. The Attorney General alleges the inhalation unit risk constitutes an ambient air standard for EO in the area near the Santa Teresa Plant, and he implies that the National Air Toxics Assessment shows actual harm to residents near the plant. EPA disagrees on both points. As for the inhalation unit risk, EPA notes that it is a rate in a toxicological equation and not an ambient air standard, and EPA specifically warns the National Air Toxics Assessment provides no data on actual EO concentrations at any specific location and it provides no data on actual risk in neighborhoods.[38] There is no reason EPA's scientific judgment should be second-guessed by a judge or jury on these technical issues. Instead, EPA and NMED are in the best position to decide whether the inhalation unit risk is an ambient air standard or whether the National Air Toxics Assessment shows any actual harm.

Similarly, the trial court will be called upon to assess the toxicological properties and long-term health risks of EO. In this case, the trial court and jury would need, for example, to (1)

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37 *Id*. at 844 (D.N.M. 1994) (staying case where EPA and NMED were addressing site issues).

38 EPA states that the NATA should "*not*" be used to characterize or compare EO risks or exposures for individuals in neighborhoods. https://www.epa.gov/national-air-toxics-assessment/nata-frequent-questions#background4 General Background Q4. EPA further warns that National Air Toxics Assessment assessments should "not*"* be used: "**to pinpoint specific risk values in small areas such a census tract; to characterize or compare risks at local levels (such as between neighborhoods)** … [or to] **to control specific sources or pollutants ….**" https://www.epa.gov/national-air-toxics-assessment/nata-overview (emphasis added).

quantify the human health and environmental risks associated with emission of EO; (2) establish the quantity and concentration of EO emitted from various industrial locations; (3) determine the naturally occurring background concentration of EO in the Santa Teresa area; (4) establish whether fugitive EO emissions specifically create any hazards above and beyond the naturally occurring background, and (5) weigh the cost and feasibility of mitigating EO emissions from specific activities such as opening and closing doors. As various courts have recognized, resolving these types of technical issues is generally outside the conventional competence of judges.[39] Accordingly, the Court would be grappling with the *exact* same EO scientific issues currently being evaluated by the EPA as it reevaluates the current Subpart O requirements for sterilizers. That overlap poses an obvious risk of conflict with EPA's expert determinations in this area.

As for the third and fourth *Schwartzman* factors, EPA has been regulating EO emissions since the early 1990s, and EPA has updated and amended its EO regulations many times.[40] Just after the National Air Toxics Assessment report was issued in 2018, EPA initiated an extensive review of EO use and emissions at commercial sterilizers. In its December 12, 2019 Advance Notice of Proposed Rulemaking, EPA provided notice that it intended to revise its EO standards for sterilization facilities. [41] In that notice, EPA sought information and comment on potential control measures for fugitive emissions of EO. Last year on June 12, 2020, EPA published notice of a proposed information collection" on EO emissions at commercial sterilizers.[42] And just a few

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39 *See N.C. ex rel. Cooper v. TVA*, 615 F. 3d 291, 305 (4th Cir. 2010) (noting issues implicated by emissions controls "require[] a very high degree of specialized knowledge in chemistry, medicine, meteorology, biology, engineering, and other relevant fields that [Congress thought] agencies rather than courts were likely to possess."); *Amer. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 428 (2011) ("[j]udges lack the scientific, economic, and technological resources an agency can utilize").

40 https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities

41 https://www.govinfo.gov/content/pkg/FR-2019-12-12/pdf/2019-26804.pdf

42 85 Fed. Reg. 35931(June 12, 2020).

months ago, on May 10, 2021, EPA gave notice that it was collecting additional information related to EO emissions at commercial sterilizers.[43]

This very type of information collection and investigation has been recognized by courts as sufficient initiation of an "agency proceeding" to justify applying the doctrine of primary jurisdiction.[44] In this case, there is no evidence these agencies are ignoring questions related to EO. To the contrary: EPA has been more involved in reassessing EO use, controls and emissions in the last two years than at any time since the EO regulations were developed in 1994.

Even more fundamentally, NMED should be given the opportunity to address these issues in the first instance, as has been made clear by both EPA and the New Mexico Legislature. EPA delegated substantial responsibility for regulating EO emissions in the State to NMED.[45] When the New Mexico Legislature created NMED in 1991, [46] the Legislature stated the purpose was to "establish a **single** department to administer the laws and exercise the functions relating to the environment formerly administered and exercised by the health and environment department."[47] Even the Attorney General agrees NMED is the "exclusive" agency for environmental standard-setting in the State. In Formal Opinion #87-48, the Attorney General stated: the New Mexico Legislature "intended to give EID [now known as NMED] "**exclusive, statewide authority to**

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43 86 Fed. Reg. 24862 (May 10, 2021).

44 *See, e.g., Norvell*, 1973-NMSC-051, ¶ 43, 85 N.M. at 172 (applying primary jurisdiction doctrine in part because state agency was "studying the problem"); *Schwartzman, Inc.* 857 F. Supp. At 842 (applying doctrine in part because EPA had "already begun the process of initiating a remedial investigation and feasibility study"); *In re "Agent Orange" Product Liability Litigation*, 475 F. Supp. 928, 933 (E.D.N.Y. 1979) (applying doctrine in part because EPA had "announc[ed] its intention to hold hearings").

45 40 C.F.R. 63.99(a)(32). See also https://www.govinfo.gov/content/pkg/FR-2018-09-12/pdf/2018-19801.pdf

46 NMSA 1978, Sections 9-7A-1 to -15 (1991, as amended through 2005).

47 NMSA 1978, § 9-7A-3 (1991) (emphasis added).

**promulgate and enforce regulations and standards** in those [i.e., environmental management"] areas."[48]

Over the past month, NMED has been evaluating an application for a Technical Revision submitted by Sterigenics to amend to its air quality permit and implement several voluntary air quality controls.[49] In considering that permit revision, NMED can determine if additional EO controls and practices are needed at the Santa Teresa Plant. And if Sterigenics disagrees with any new EO-controls required by NMED, New Mexico law provides that Sterigenics can challenge that decision. NMED likely would resolve the alleged EO-emission issues, if necessary, years before a tort lawsuit would make it to a jury. Similarly, if NMED believes current Subpart O regulations do not go far enough to cover EO emissions from garage doors, NMED can initiate a rulemaking on those issues, subject to judicial review at the behest of aggrieved parties.

## III. INDUSTRY IN NEW MEXICO REQUIRES CLEAR ENVIRONMENTAL REQUIREMENTS CREATED AND ENFORCED BY AGENCIES WITH SPECIALIZED EXPERTISE, NOT *AD HOC* LIMITATIONS DEVELOPED BY TRIAL COURTS OR JURIES.

While this case involves EO-emissions at a commercial sterilizer in New Mexico, the fundamental issues are national in scope. Allowing EO use, management, and emission standards

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48 Opinion of Attorney General Hal Stratton, #87-48 (Aug. 24, 1987); *see also N.M. Municipal League, Inc. v. N.M. Envtl. Bd*., 1975-NMCA-083, 540 P.2d 248, 266-67 ("it was the intention of the legislature to give the Environmental Improvement Board state-wide, paramount authority to 'enforce regulations and standards' in the various areas listed and that all other entities of government and political subdivisions thereof must conform"); *Interstate Nuclear Corp. v. City of Santa Fe*, 179 F. Supp. 2d 1253, 1259 (D.N.M. 2000) ("legislature intended to give NMED exclusive state-wide authority to promulgate and enforce regulations in those areas") (internal citations and quotations omitted), referencing N.M.A.G. Op. No. 87-48 (1987); *Moongate Water Co. v. State*, 1995-NMCA-084, 120 N.M. 399, 403 ("It was the legislature's intent to give the Environmental Improvement Board, and therefore the Environment Department, paramount authority to enforce its regulations and standards.").

49 The Technical Revision to NSR Permit No. 0733-M15-R1 was submitted to NMED by Sterigenics on May 7, 2021. The application seeks approval to install certain other voluntary measures, noting that the total amount of EO is so low the unit is below the NMAC regulatory standards.

to be fashioned and hammered out in a tort case by a local jury applying malleable public nuisance standards is not in the best interests of health care, good science, or sensible regulation.

### A. The Already Strained Supply of Medical Products Sterilized by EO Will Be Jeopardized Further if this Tort Lawsuit is Allowed to Proceed.

In Count I of his Complaint, the Attorney General contended that "[t]he seriousness of the risk created" by EO emissions "far outweighs any social utility of Defendants' conduct." ¶167. Noticeably absent from his discussion, however, was any reference to the implications of shutting down the Santa Teresa Plant for hospitals, surgical centers, and doctor's offices in New Mexico, as well as thousands of patients who require EO-sterilized medical products each day. Weighing these implications is an essential element of agency decisions in the rulemaking process.

Any *ad hoc* creation of new and potentially conflicting EO emission standards in a tort suit will jeopardize the supply of EO sterilized products and weaken an already strained healthcare supply chain—in New Mexico and across the U.S. According to the FDA, approximately 50% of medical products in the U.S. that require sterilization are sterilized using ethylene oxide.[50] On October 25, 2019, the FDA expressed its concern over the availability of adequate EO sterilization facilities:

> Because the number of ethylene oxide contract sterilization facilities in the U.S. is limited, we are very concerned that additional facility closures could severely impact the supply of sterile medical devices to health care delivery organizations that depend on those devices to take care of patients. The impact resulting from closure of these and perhaps more facilities will be difficult to reverse, and ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care.[51]

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50 https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices.

51 https://www.congress.gov/116/meeting/house/110247/documents/HHRG-116-IF18-20191120-SD011.pdf. In other statements, FDA noted it was "closely monitoring the supply chain effects of closures and potential closures of certain facilities that use ethylene oxide to sterilize medical devices prior to their use. The Agency is concerned about the future availability of sterile medical devices and the potential for medical device shortages that might impact patient care." https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-facility-updates

The more that trial courts and juries determine EO-standards and practices after-the-fact according to vague and unpredictable state tort law standards, the more uncertainty medical product manufacturers will face.

If this nuisance case moves forward, no medical product manufacturer (and, indeed, no other manufacturer with emissions that are similarly regulated under the Clean Air Act) will ever know the full range of environmental requirements in New Mexico, when they apply, when they don't apply, who they apply to, and what specific actions are necessary to control emissions and discharges. EO regulation will become a patchwork of district-by-district judicial or jury decisions on what EO requirements allegedly affect human health and the environment, which EO control strategies are achievable, and whether EO emissions adversely affect human health and the environment. As a practical matter, however inconsistent the results may be with rational regulation under the Clean Air Act, it may become necessary for a sterilizer to seek permission of the Attorney General whenever it opens doors and closes doors if any substance is emitted. Allowing this case to go forward at this time as a tort matter will only confuse the existing EO-regulatory framework now being applied and reassessed by EPA and NMED.

A related concern for medical product sterilizers in particular and regulated industry in general is that, if this case proceeds down the normal tort path, both EPA and NMED, the two agencies responsible for regulating EO, will be cut out of the process to develop EO use and emissions standards and practices. The Clean Air Act's and the Air Quality Control Act's proper functioning depends on the certainty and predictability Congress (and the New Mexico Legislature) designed into the agency standard-setting process.

Medical product and healthcare companies—in fact, all manufacturers in New Mexico—should not have to spend millions of dollars on complex, technical regulations only to then have

to determine if they meet undefined standards set by an Attorney General without input from either EPA or the NMED. EO-emission standards developed in tort lawsuits will result in vague and uncertain standards that will create a confused patchwork of environmental standards to the detriment of industry and the environment alike. If the Attorney General can bypass EPA's Subpart O regulations for medical product sterilizers, ignore the NMED's statutory duty to regulate human health and the environment (including EO itself), and sidestep the importance of OSHA in setting worker exposure standards to EO, then environmental regulation in New Mexico will have little meaning for manufacturers in the State.

Under the Attorney General's regulation-by-tort approach, a company contemplating construction or expansion of a critical medical device manufacturing facility will have no way of knowing, before substantially investing in the project, whether the contemplated facility would actually meet environmental standards. Commercial sterilizers in the State of New Mexico would need to wait on the uncertain twists and turns of litigation to know what they are supposed to do, or not do. Waiting for medical device EO-sterilization standards to be set in litigation by courts and juries, businesses will be constantly on the lookout for additional costs, wasted investments, unexpected demands, and protracted legal battles.

If the Attorney General can classify EO emissions—even if exempted under Subpart O enforced by EPA and NMED and below OSHA's permissible exposure limit—as "public nuisance," the continued supply of safe and reliable medical devices will be far less certain, particularly in this State. Just as the NMED cannot devise new EO requirements without complying with the New Mexico Air Quality Control Act's notice and hearing rulemaking process, neither should the Plaintiff be permitted to craft new day-to-day requirements in public nuisance lawsuit.

### B. The "Public Nuisance" Approach to Air Quality Regulation is Fundamentally Unfair to Medical Device Manufacturers and Other Manufacturers in New Mexico and Across the Nation.

This case illustrates why novel public nuisance lawsuits are an inappropriate, ineffective, and a fundamentally unfair way to regulate one of the most technical, and most important, issues in health care today. As one court explained, "[g]iving a green light to a common-law public nuisance cause of action" in situations like this would "likely open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities."[52] It is precisely for this reason that courts have rejected end-run "public nuisance" claims, noting that public nuisance (properly understood) cannot accommodate their claims or be used to sidestep compliance with the requirements of other, more appropriate causes of action.[53]

From an environmental law perspective, ill-defined public nuisance suits like this one undermine the purpose and intent of the Clean Air Act, demean the role of specialized agencies such as EPA, NMED, OSHA, and the FDA, and interfere with the safe supply of critical medical

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[52] *See generally* U.S. Chamber Inst. for Legal Reform, *Waking the Litigation Monster: The Misuse of Public Nuisance* (2019), https://instituteforlegalreform.com/research/waking-the-litigation-monster-themisuse-of-public-nuisance/; *People v. Sturm, Ruger & Co.*, 309 A.D.2d 91, 96 (N.Y. App. Div. 2003); *see also Detroit Bd. of Educ. v. Celotex Corp.*, 493 N.W.2d 513, 521 (Mich. Ct. App. 1992) (holding that allowing a nuisance claim in asbestos cases "would significantly expand, with unpredictable consequences, the remedies already available to persons injured by products, and not merely asbestos products").

[53] *See, e.g.*, *Tioga Pub. Sch. Dist. No. 15 v. U.S. Gypsum* Co., 984 F.2d 915, 920 (8th Cir. 1993) (noting that, as to asbestos claims, "[a]ll of the courts that . . . considered the issue . . . rejected nuisance as a theory of recovery"); *Celotex Corp.,* 493 N.W.2d at 521 ("[T]he public would not be served by neutralizing the limitation period by labeling a products liability claim as a nuisance claim."); *Texas v. Am. Tobacco Co.*, 14 F. Supp. 2d 956, 973 (E.D. Tex. 1997) (in tobacco suit, explaining that it was "unwilling to accept the State's invitation to expand a claim for public nuisance beyond its grounding in real property"); *In re Lead Paint Litig.,* 924 A.2d 484, 494–95 (N.J. 2007) (concluding that "permit[ting] these complaints to proceed . . . would stretch the concept of public nuisance far beyond recognition and would create a new and entirely unbounded tort antithetical to the meaning and inherent theoretical limitations of the tort of public nuisance"); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1116 (Ill. 2004) (dismissing nuisance suit against gun manufacturers, noting that "there is [no] public right to be free from the threat that some individuals may use an otherwise legal product (be it a gun, liquor, a car, a cell phone, or some other instrumentality) in a manner that may create a risk of harm to another").

products to patients through the nation. Public nuisance lawsuits circumvent public participation in the rulemaking process, bypass the technical expertise of the agencies to which Congress (and the New Mexico Legislature) delegated standard-setting authority, and force trial courts and juries needlessly to tackle complex scientific problems and competing policy values.

Public nuisance lawsuits turn courts into duplicate Clean Air Act regulators instead of reviewers of agency action, with standards of review being set not by expert agencies but by jurors who lack technical knowledge and expertise. Even for sources located only miles apart, or the same source being sued in two different district courts, nuisance standards grant such wide decision-making authority as to seriously undermine any attempts to predict their outcomes. The predictable federal regulatory framework governing EO standards would be undermined by injunctions and damage awards imposed on courts on a case-by-case basis, resulting in identical sources across the country becoming subject to different requirements. Allowing these very complex EO-emission issues to be decided in a public nuisance case would destroy the regulatory certainty that air quality permits are supposed to provide to regulated industry.[54]

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[54] *Amici* note the Attorney General has submitted a declaration signed by Environment Secretary Kenney indicating he does not support the application of the primary jurisdiction doctrine in this litigation. In Paragraph 9, the declaration states "NMED regulations concerning [EO] emissions and permits under the Air Quality Control Act ('AQCA') require the use of certain emission control technologies, but do not impose limits or requirements with respect to emissions that result from efforts to bypass, subvert, or circumvent those technologies." With due respect to the Secretary, this statement minimizes NMED's authority. *Espinosa v. Roswell Tower, Inc.*, 910 P.2d 940, 944 (NMED is responsible for air quality management and authorized to "exercise all powers reasonable and necessary to accomplish its statutory duties." (citing NMSA 1978, §§ 74–1–7(A)(4), 74–1–6(H)–6(I))); *Copar Pumice Co. v. Morris*, No. Civ. 07-79, 2007 WL 5685122, at *3 (D.N.M. Sept. 10, 2007) ("NMED is statutorily responsible for environmental management, and is required to maintain, develop, and enforce rules and standards in a variety of areas, including air quality management, as provided in the Air Quality Control Act."). NMED has broad duties under the Act regarding any circumstances where NMED "has reasonable cause to believe is or will become a source contributing to air pollution." NMSA 1978, § 74-2-5.1(A). The Legislature assigned to the Secretary the responsibility to bring suit or issue orders in any case where he determines "that a source of combination of sources presents an imminent and substantial endangerment to the public health or welfare or to the environment." *Id.* § 74-2-10. Accordingly, NMED has broad authority to enforce its regulations and conditions if a permittee has "bypassed, subverted, or circumvented" specific permit conditions.

The impossible challenge created by the Attorney General's "tort regulation" approach is obvious. If a company like Sterigenics has complied with EPA, OSHA, FDA, and NMED regulations concerning EO use, management, monitoring, and emissions, how would it ever know how to meet the "common law" EO emissions duty the Attorney General now says should control? Apparently, to decide whether an EO-related act or activity is now subject to that "common law" EO duty, commercial sterilizers would be required to contact the Attorney General, explain the issues, point to the technical issue that may (or may not) be regulated, and seek permission of the Attorney General, not NMED, whenever they perform such routine activities as opening and closing doors at an EO sterilizer.

Fundamentally, the "public nuisance" tactic taken by the Attorney General is the wrong way to implement new standards, practices and procedures in New Mexico. As a matter of basic fairness, it is essential that environmental regulatory expectations for medical device manufacturers in the State—and industry in general—be clearly communicated and consistent at the outset. EPA and NMED, through rulemaking, can and should provide that certainty.[55]

The Attorney General's public nuisance lawsuit does the opposite of this, replacing rulemaking by expert agencies, subject to appropriate procedural protections under administrative law. with after the fact regulation by litigation. The lawsuit cuts NMED out of the regulatory picture, contrary to the clear instructions by the New Mexico Legislature that NMED is the "single" environmental agency in the State. If the State can turn EO emissions—no matter how small, and even if EPA does not believe they warrant a permit—into a "public nuisance," the continued supply of safe and reliable medical devices becomes far less certain, particularly in this

[55] *See TVA,* 615 F.3d at 305 ("[T]he rulemaking process has the benefits of providing proactive instead of reactive control, creating opportunities for notice and comment, allowing flexibility in developing rules, [] lowering the likelihood of disturbing reliance interests . . . and also makes the resulting rules readily accessible in a single location.")

State. And while that alone is bad enough, the implications go far beyond EO, as the legal rationale for the Attorney General's theory is not limited to any particular chemical substance. If the tort suit proceeds, the mere litigation of these claims will create practical problems for manufacturers who will face a confused patchwork of vague and uncertain nuisance standards in addition to environmental standards.[56]

From a broader perspective, this "know it when you see it" public nuisance approach would have widespread, unexpected effects on New Mexico industry. Many questions would arise, such as: are air emissions from nail salons, which include certain detectable levels of benzene (which, like EO, is a Hazardous Air Pollutant under the Clean Air Act), prohibited under this approach, no matter how small? Are emissions of imperceptible benzene emissions from filling a car with gasoline or volatile organic compounds from breweries also "public nuisances"? Under the new approach implied by the Attorney General's lawsuit, they probably are. To constitute a public nuisance under this approach, no determination of an actual human health hazard is required, and the existence of background EO concentrations is not assessed.

Applying the primary-jurisdiction doctrine cures these uncertainties. Dismissal promotes legal and regulatory clarity and predictability which have been especially vital for medical device manufacturers as they endeavor to meet the essential services demanded by sick patients during COVID-19. [57] As the Supreme Court counseled over seventy years ago, "[u]niformity and consistency in the regulation of business entrusted to a particular agency are secured . . . by

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56 *Id.* at 294.

57 *W. Pac. R. Co.*, 352 U.S. at 63-64; *see also Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 673 (2003) (Breyer, J., concurring) (primary jurisdiction "seeks to produce better informed and uniform legal rulings by allowing courts to take advantage of an agency's specialized knowledge, expertise, and central position within a regulatory regime")

preliminary resort . . . to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure."[58]

**CONCLUSION**

*Amici* respectfully suggest this Court should exercise its discretion to dismiss or stay this case under the doctrine of primary jurisdiction.

Respectfully submitted,

/s/ Dalva L. Moellenberg
Dalva L. Moellenberg
Gallagher & Kennedy, P.A.
1239 Paseo de Peralta
Santa Fe, New Mexico 87501
505-982-9523
DLM@gknet.com

Douglas A. Henderson*
King & Spalding LLP
1180 Peachtree Street
Atlanta, Georgia
404-572-2769
dhenderson@kslaw.com
**Pro Hac Application Pending*

[58] *Far E. Conference v. United States*, 342 U.S. 570, 574–75 (1952).

WE FURTHER CERTIFY that a true and correct copy of the foregoing was submitted through the Odyssey Electric Filing System for filing and service to all counsel of record and served all counsel of record this 4th day of June, 2021.

GALLAGHER & KENNEDY, P.A.

By: /s/ Dalva L. Moellenberg
Dalva L. Moellenberg

Exhibit A

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| District Court Jefferson County, State of Colorado<br>100 Jefferson County Parkway<br>Golden, Colorado 80401<br><br>DATE FILED: February 16, 2021 3:21 PM<br>CASE NUMBER: 2019CV31822 | ▲ COURT USE ONLY ▲ |
| **Plaintiffs: EDWARD SMITH JR., individually and on behalf of all others similarly situated**<br><br>**v.**<br><br>**Defendants: TERUMO BCT, INC., TERUMO BCT STERILIZATION SERVICES, INC.** | Case Number:<br><br>**2019CV031822**<br><br>Division 15 |
| **ORDER: DEFENDANTS' MOTION TO DISMISS** | |

This matter comes before this Court on Defendants Terumo BCT, Inc. and Terumo BCT Sterilization Services, Inc.'s ("Defendants") Motion to Dismiss ("Motion") filed on March 9, 2020. After reviewing the Motion; Plaintiff's Response and Opposition filed on April 20, 2020; and Defendants' Reply filed on May 11, 2020; as well as relevant portions of the file and applicable legal authority, including the submissions by Defendants on May 15, 2020; June 5, 2020; and October 8, 2020, the Court enters this order. The Motion is GRANTED for the reasons that follow.

## I. BACKGROUND

Defendants are the owners and operators of manufacturing and sterilization facilities in Lakewood, Colorado ("Lakewood Facilities"). *Pl.'s Compl.* ¶ 1. Defendants sterilize medical equipment using Ethylene Oxide (EtO), which is a colorless and odorless gas and a known carcinogen. *Id.* at ¶¶ 2-4, 14-15, 20-28. Plaintiff Edward Smith ("Plaintiff") resides near the Lakewood Facilities and alleges that he, and unidentified class members living in certain census tracts, have been exposed to large amounts of toxic EtO gas resulting from Defendants' alleged dangerous and reckless emission of EtO from the Lakewood Facilities since 1988. *Id.* at ¶¶ 4-5, 18-19, 44, 47. Plaintiff alleges that he has "inhaled toxic carcinogenic gasses" and is therefore at an increased risk for developing cancer, illness, or disease. *Id.* at ¶ 42, 47-48. He asserts that it is "reasonably medically necessary to undergo and incur the cost of diagnostic testing for the early detection of illness, disease process or disease related to [EtO]" in order to "ensure that illness and disease processes can be immediately identified and aggressively treated." *Id.* at ¶¶ 6, 18-19, 48.

Plaintiff filed this action against Defendants on December 10, 2019, as a class action on behalf of himself and other similarly-situated residents of the land surrounding the Lakewood Facilities. Plaintiff alleges (1) negligence, (2) strict liability for ultrahazardous activity, (3) private nuisance, and (4) public nuisance. Plaintiff seeks damages to include the cost of a program for diagnostic testing. *Id.* at ¶ 49-52. Alternatively, Plaintiff seeks the establishment of a court-supervised program of diagnostic testing through injunctive relief. *Id.* at ¶ 52. Defendants move for dismissal pursuant to C.R.C.P. 12(b)(5).

## II. LAW AND ANALYSIS

### A. 12(b)(5)

A court may dismiss a complaint for "failure to state a claim upon which relief can be granted." C.R.C.P. 12(b)(5). The purpose of a motion to dismiss for failure to state a claim is to test the formal sufficiency of the complaint. *Dorman v. Petrol Aspen, Inc.*, 914 P.2d 909, 911 (Colo. 1996). To survive a Rule 12(b)(5) motion, the complaint must plead sufficient facts, taken as true and in the light most favorable to the plaintiff, to state a claim for relief that is plausible on its face. *Warne v. Hall*, 373 P.3d 588, 589-90 and 595 (Colo. 2016) (embracing the plausibility standard in federal cases *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) as applicable in Colorado).

A properly pled complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief." C.R.C.P. 8(a)(2). While Rule 8 does not require detailed factual allegations, it demands "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Iqbal*, 556 U.S. at 678. "Factual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *see also Warne*, 373 P.3d at 591. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 677. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* at 678 (internal quotations and citations omitted).

Courts are to apply a two-step approach when considering a motion to dismiss. *Warne*, 373 P.3d at 591 (citing *Iqbal*, 556 U.S. at 678-69). First the court "must accept as true all the allegations contained in a complaint;" however, legal conclusions are not entitled to the assumption of truth. *Iqbal*, 556 U.S. at 678. Second, the court must consider whether the factual allegations in the complaint allege a plausible claim for relief. *Id.* at 679.

"In deciding whether to dismiss, the court may consider only the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference in the pleadings and matters of which the court may take judicial notice." *Walker v. Van Laningham*, 148 P.3d 391, 397 (Colo. App. 2006). A "motion to dismiss is properly granted when the plaintiff's factual allegations cannot support a claim as a matter of law." *BRW Inc. v. Dufficy & Sons, Inc.*, 99 P.3d 66, 71 (Colo. 2004).

In this case, the Court determines whether the facts presented by Plaintiff, assumed to be true, are sufficient to support the claims of negligence, strict liability, private nuisance, and public nuisance regarding Plaintiff's exposure to Defendants' emissions of EtO from their medical equipment sterilization facility.

B. **Tort Claims: Injury**

The main issue for the Court to address in considering Defendants' Motion to Dismiss is whether Plaintiff has pleaded a cognizable injury. Defendants argue that Plaintiff has not asserted a present physical injury and that increased risk or future theoretical injuries are insufficient to support tort claims. Plaintiff asserts that he has already been exposed to EtO emissions, has therefore already suffered an increased risk of cancer or other serious illness, and has a present need for diagnostic testing that is sufficient to establish present injury. In short, the parties dispute whether Plaintiff has pleaded an injury upon which relief can be granted, and Colorado courts have not squarely addressed this issue in this context.

When determining whether a plaintiff suffered an injury, the Colorado Supreme Court has held and reaffirmed that "a person cannot pursue a tort claim for future death, future physical injury, or future property damage," making it clear that the plaintiff must be currently injured to make a tort claim. *Open Door Ministries v. Lipschuetz*, 373 P.3d 575, 579 (Colo. 2016) (analyzing the meaning of "injury" for purposes of the Colorado Governmental Immunity Act and holding that the Act applies only to claims that allege an injury has already occurred); *see also Isaac v. Am. Heritage Bank & Tr. Co.*, 675 P.2d 742, 744 (Colo. 1984) (noting that one of the basic principles of law is that a party may not recover damages if he has not suffered an injury—"[t]o warrant the recovery of damages, there must be both a right of action for a wrong inflicted by the defendant and damage resulting to the plaintiff therefrom."). The Tenth Circuit reinforced the idea that there must be an actual injury to the Plaintiff, determining that "negligence is not actionable in Colorado unless it results in physical damage to persons or property." *Adams-Arapahoe School Dist. No. 28-J v. GAF Corp.*, 959 F.2d 868, 871 (10th Cir. 1992) (holding that damage by virtue of the mere presence of vinyl asbestos tile is not recoverable under Colorado tort law). The issue presented in this case is whether allegations of exposure to a toxic substance, which triggers a claimed need for medical monitoring, is sufficient to constitute injury.

This Court finds that proof of exposure to a toxic chemical, as alleged in this case, is inadequate to support a cause of action for toxic-tort related injury. *See* 57 Am. Jur. Trials 395 (1995). In surveying various cases that have addressed this and similar topics, this Court finds other courts that hold that allegations of mere exposure to toxic substances are not sufficient to state a claim, absent some proof of manifestation of a physical injury. *See id.* (citing *Locke v. Johns-Manville Corp.*, 275 S.E.2d 900 (Va. 1981) (holding that legally and medically there was no injury upon inhalation of asbestos fibers); *In re Hawaii Fed. Asbestos Cases*, 734 F. Supp. 1563 (D.C. Hawaii 1990) (mere presence of asbestos fibers, pleural thickening in the lung unaccompanied by an objectively verifiable functional impairment is not enough, even with claimant's subjective testimony as to shortness of breath and fatigue); *Schweitzer v. Consolidated Rail Corp.*, 758 F.2d 936 (3rd Cir. 1985)). *See also Barker v. Naik*, 2018 WL 3824376 at *3 (S.D.W.Va. Aug. 10, 2018) (granting a motion to dismiss because plaintiffs'

allegations they were reasonably certain to suffer "effects of physical exposure to noxious emissions from the fire" was insufficient to plead a present injury); *Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d 88 (4th Cir. 2011) (holding the presence of a toxic substance in plaintiffs' blood, standing alone, was insufficient to establish harm or injury for the purposes of proving a negligence claim under West Virginia law).

Here, Plaintiff argues that "a complaining party may satisfy the actual injury requirement by demonstrating that the challenged action has caused, or threatens to cause, economic injury." *United Airlines v. City & Cty. of Denver*, 973 P.2d 647, 652 (Colo. App. 1998). The injury must be direct and palpable. *Id*. Specifically, Plaintiff alleges that the current economic costs of medical monitoring are sufficient to establish injury. However, the Court notes that *United Airlines* was not a tort case, but rather a case regarding taxation and statutory penalties and interest under municipal code. *Id.* at 652-53 (noting that "if a party suffers no injury in fact, or suffers injury in fact but not from a violation of a legal right, no relief can be afforded, and the case should be dismissed for lack of standing.").

This Court finds that the claim of economic injury for medical monitoring is based solely on the potential risk for future illness or disease and is not a present injury in itself. In other words, this Court disagrees with Plaintiff's contention that the need for medical testing or monitoring is a cognizable injury in a tort action. In so finding, this Court finds the analysis in *Berry v. City of Chicago*, 2020 WL 5668974 (September 24, 2020) persuasive. In *Berry*, the Supreme Court of Illinois addressed plaintiffs' allegations that replacing water mains and meters created an increased risk that lead would be dislodged or leach into residential service lines and water supplies, even though plaintiffs did not exhibit any current physical impairment or dysfunction caused by the ingestion of the water. *Id* at ¶¶ 6-15. Here, as in *Berry*, "[w]ithout an increased risk of future harm, plaintiffs would have no basis to seek medical monitoring." *Id.* at ¶ 37. "In other words, plaintiffs' allegation that they require 'diagnostic medical testing' is simply another way of saying they have been subjected to an increased risk of harm." *Id.* (citing Restatement (Third) of Torts, Liability for Physical & Emotional Harm § 4, cmt. C (2010)). In finding that increased risk of harm is not, itself, an injury, this Court finds persuasive that the "long standing and primary purpose of tort law is not to punish or deter the creation of this risk but rather to compensate victims when the creation of risk tortiously manifests into harm." *Id.* at ¶ 33. The *Berry* court goes on to note that a plaintiff who suffers bodily harm may recover for an increased risk of future harm as an element of damages but may not recover solely for the defendant's creation of an increased risk of harm. *Id.* at ¶ 38.

The Court finds that Plaintiff has blurred the line between establishing injury and damages. As the Supreme Court of Michigan noted, "if the alleged damages cited by plaintiffs were incurred in anticipation of possible future injury rather than in response to present injuries, these pecuniary losses are not derived from an injury that is cognizable under Michigan tort law [which requires more than a merely speculative injury]. *Henry v. Dow Chemical Co.*, 701 N.W.2d 684, 689-90 (Mich. 2005) (affirming the principle that "a plaintiff must demonstrate a present physical injury *in addition to* economic losses that result from that injury in order to recover under a negligence theory."). In arguing that the need to pay for medical monitoring is itself a present injury sufficient to sustain a cause of action for negligence, "plaintiffs attempt to blur the distinction between 'injury' and 'damages.'" *Id.* at 691. "[T]hese economic losses are

wholly derivative of a *possible, future* injury rather than an *actual, present* injury." *Id.* (emphasis in original). Simply stated, a "financial 'injury' is simply not a present physical injury, and thus not cognizable under our tort system." *Id; see also* 22 *Am. Jur. 2d Damages* § 2 (2020) ("Although the words 'damages,' 'damage,' and 'injury' are sometimes used synonymously, there is a material distinction between them. Injury is the illegal invasion of a legal right; damage is the loss, hurt, or harm that results from the injury; and damages are the recompense or compensation awarded for the damage suffered.").

Here, Plaintiff claims he and the putative class members have suffered significant exposure to hazardous and carcinogenic EtO gases, "have some of the highest cancer risks in the United States," "are up to 14 times more likely to develop cancer than the average American," and "are at an increased risk of illness, disease process and/or disease." Compl. at ¶ 5, 45-48. Plaintiff claims they have therefore "incurred the need to obtain diagnostic testing for the early detection of illness, disease process, or disease as a result of the increased risk caused by their exposure to the toxic [EtO] released by Defendants, and to ensure that illness and disease processes can be immediately identified and aggressively treated." Compl. at ¶ 6, 48. However, Plaintiff does not allege he has been diagnosed with cancer or any other serious illness or disease. Plaintiff has also not alleged any concrete facts that evidence of EtO exposure is present in his body—in other words, Plaintiff concludes he has been exposed to EtO based on how the chemical disperses in the atmosphere but provides no tangible information to support the claim that he has been exposed or has experienced any physical manifestation of injury from the exposure. Even taking Plaintiff's allegations of exposure and heightened risk of developing disease as true, the Court finds exposure to a toxic substance does not, by itself, establish injury for an action in tort.

C. **Claim for Medical Monitoring**

Although Colorado state courts have never explicitly adopted a separate tort claim for medical monitoring, Plaintiff alleges that the cost of diagnostic testing for the early detection of illness or disease should be recoverable under Colorado law. In so arguing, Plaintiff relies primarily on federal district court cases that provide support for a claim or remedy of medical monitoring.

"The theory behind a request for medical monitoring is that when a plaintiff is exposed to a hazardous substance due to a defendant's tortious acts or omissions, it may be necessary to seek periodic medical monitoring to determine whether plaintiff has contracted a disease and that the defendant may be required to pay the cost of such monitoring." *Satsky v. Paramount Commc'ns, Inc.*, 1996 WL 1062376, at *5 (D. Colo. Mar. 13, 1996) (citing *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825 (D.C. Cir. 1984)). "A medical monitoring request compensates a plaintiff for diagnostic treatment actually administered, a tangible and quantifiable item of damage caused by defendant's tortious conduct." *Id.* (citing *Cook v. Rockwell Int'l Corp.*, 755 F. Supp. 1468, 1477 (D. Colo. 1991)).

The "question of the validity of medical monitoring claims absent a present physical injury is one that 'has divided state and federal courts in recent decades.'" *Bell v. 3M Co.*, 344 F.Supp. 3d 1207, 1223 (D. Colo. 2018) (listing cases on both sides—courts that have found

medical monitoring does not constitute a valid cause of action absent a present physical injury and courts that have reached the opposite conclusion and have recognized medical monitoring as either an independent cause of action or as a remedy). After reviewing this divide, the United States District Court for the District of Colorado has twice predicted that in an appropriate case, the Colorado Supreme Court may recognize a claim for medical monitoring absent present physical injury and outlined the elements of a potential cause of action for medical monitoring: (1) the plaintiff has suffered a significant exposure to a hazardous substance through the tortious actions of the defendant; (2) as a proximate result of this exposure, the plaintiff suffers from an increased risk of contracting a serious latent disease; (3) that increased risk makes periodic diagnostic medical examinations reasonably necessary; and (4) monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial. *Bell*, 344 F.Supp. 3d at 1225; *see also Cook*, 755 F. Supp. at 1477 ("Although Colorado has yet to do so, I conclude that the Colorado Supreme Court would probably recognize, in an appropriate case, a tort claim for medical monitoring."). Stated differently, a medical monitoring plaintiff must demonstrate that the medical monitoring at issue is something greater or different than would be recommended as a matter of general health care for the public at large in the absence of exposure. *See Sadler v. PacifiCare of Nev.*, 340 P.3d 1264, 1271 (Nev. 2014) (citing *Redland Soccer Club, Inc. v. Dep't of the Army and Dep't of Defense of the U.S.*, 696 A.2d 137, 146 (Penn. 1997)).

However, the courts in both *Cook* and *Bell* found pleading deficiencies. In *Cook*, plaintiffs failed to allege that they had been significantly exposed to a proven hazardous or toxic substance and had only alleged a risk of exposure. *Cook*, 755 F.Supp. at 1471, 1477 (granting leave to amend to correct the pleading deficiency). In *Bell*, the court held that while plaintiffs had plausibly pleaded exposure and the increased risk of contracting a serious illness, they failed to plausibly plead that medical tests existed that were reasonable and necessary to detect latent diseases. *Bell*, 344 F.Supp. 3d. at 1226-27 (granting dismissal and holding that plaintiffs did not satisfactorily plead the required element that monitoring and testing procedures exist which make the early detection and treatment of latent diseases possible and beneficial where the complaint only asserted that "[m]edical tests currently exist that can determine the level of [the chemicals] in the blood" and that "bioaccumulation of elevated levels of [the chemicals] in an individual's blood significantly increases the risk of contracting a serious medical condition, [so] periodic medical examinations are both reasonable and necessary to detect latent diseases.").

Despite the predictions in *Cook* and *Bell*, this Court has not found a single Colorado case in the intervening thirty years that adopted or advanced this separate cause of action or remedy under Colorado state law.[1] Defendants assert that this Court should not expand Colorado tort law to allow a cause of action or remedy for medical monitoring, absent physical injury as discussed above, and the Court agrees. The Court declines to engage in legislative or policy-making functions, and therefore does not need to analyze whether Plaintiff here has adequately pleaded a potential medical monitoring cause of action. The Court has concerns, however, that the same pleading deficiencies present in *Cook* and *Bell* are also present here.

[1] In *Barriga v. American Family Mut. Ins. Co*., a Colorado state district court considered the claim for the costs of medical monitoring predicated on negligence. 2013 WL 8298030 (February 11, 2013). That court noted it could not find a single Colorado case addressing the precise issue, and therefore turned to a Michigan case, *Henry v. Dow Chemical Co.*, 473 N.W.2d 684 (Mich. 2005), for guidance, which this Court has discussed above. *Id.* at *11.

## III. CONCLUSION

For these reasons, the Court GRANTS the Motion to Dismiss Plaintiff's claims. Based on the Court's findings and order, the Court declines to analyze whether Plaintiff has sufficiently pleaded the other elements of each of his claims. Additionally, the Court deems MOOT Defendants' Motion to Strike Class Action Allegations, filed on March 9, 2020, and therefore declines to address the issue.

SO ORDERED this 16th day of February 2021,

BY THE COURT:

Lindsay L. VanGilder
District Court Judge