UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

STERIGENICS U.S., LLC,	)	
Plaintiff,	)	**Case No.**
v.	)	
JOHN KIM, not individually, but solely in his capacity as Acting Director of the Illinois Environmental Protection Agency, and the ILLINOIS ENVIRONMENTAL PROTECTION AGENCY,	)	
Defendants.	)	

PLAINTIFF STERIGENICS U.S., LLC'S MEMORANDUM IN SUPPORT OF ITS EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION AGAINST ENFORCEMENT OF THE SEAL ORDER DATED FEBRUARY 15, 2019

Maja C. Eaton
Gerard D. Kelly
Elizabeth M. Chiarello
Stephanie C. Stern
Kate Lambert
SIDLEY AUSTIN LLP
Firm ID No. 42418
One South Dearborn Street
Chicago, Illinois 60603
Telephone: (312) 853-7000
Facsimile: (312) 853-7036

Attorneys for Sterigenics U.S., LLC

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INTRODUCTION

Shortly after 5:00 pm on Friday, February 15, 2019, a "Seal Order" was issued by defendants Illinois Environmental Protection Agency ("IEPA") and John Kim (the Acting Director of IEPA) ("Kim"), purportedly under 415 ILCS 5/34(b), with respect to "[a]ll storage containers of ethylene oxide" at the ethylene oxide sterilization facility in Willowbrook, Illinois (the "Willowbrook facility"), operated by plaintiff Sterigenics U.S., LLC ("Sterigenics"). ***No effort whatsoever*** was made to afford Sterigenics due process. There is absolutely ***no evidence whatsoever***, either in the Seal Order or anywhere else, to suggest that the ethylene oxide storage containers at the Willowbrook facility present an "imminent and substantial endangerment to public health or welfare" (Seal Order ¶ 18 (attached as Ex. A)), which is the standard set forth in 415 ILCS 5/34(b)(2). Indeed, the reverse is true—***the ethylene oxide storage containers at the Willowbrook facility are fully compliant with every applicable law and regulation***, which the Seal Order does not refute. The Seal Order is a charade.

The Seal Order's focus on the ethylene oxide storage containers is a thinly veiled effort to circumvent the judicial process, to deny Sterigenics its Constitutional right to due process, and to shut down the Willowbrook facility, despite the fact that the facility has been operating in compliance with all statutory and regulatory requirements related to its emissions, including those of the United States Environmental Protection Agency ("USEPA") and IEPA. At the request of IEPA, the Attorney General of the State of Illinois and the State's Attorney for DuPage County, Illinois (together, the "State") filed an action in October 2018 seeking, *inter alia*, a preliminary injunction "ordering the Defendant to cease operations if warranted" (("IAG Action") Dkt. 1-1 at PageID 104). However, the State neither filed a motion for preliminary injunction with its Complaint nor in the months since. Instead, after the close-of-business on the

Friday before a holiday weekend, IEPA sought to achieve by extra-judicial diktat what it knows it cannot achieve in a court of law. Since the State filed the IAG Action, it has become increasingly clear that a sudden shut-down without due process is ***not warranted***, that there is ***no imminent and substantial endangerment***, and that, in fact, ***a shut-down is detrimental to the public interest and adversely impacts the United States healthcare system***. The Seal Order is based on neither law nor facts—it is a precipitous reaction to highly inaccurate news reports regarding grossly misunderstood science and the resulting understandable, but entirely unfounded, concerns among members of the public.

Moreover, what the Seal Order does ***not*** say is even more important than what it does say. ***Nowhere does the Seal Order identify any applicable federal or state regulation that Sterigenics is violating—nor could it***. The Seal Order (S.O. ¶¶ 6–8) cites the "2016 IRIS Evaluation" – but that is ***not*** a regulation, and as discussed below, is deeply flawed in any event. The Seal Order (*id.* at ¶¶ 11–14) cites to consultation work by the Department of Health and Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") – but that is ***not*** a regulation, and as discussed below, is even more deeply flawed than the "2016 IRIS Evaluation" on which it relies. Finally, the Seal Order (*id.* at ¶¶ 15–17) cites USEPA's National Emission Standard for Hazardous Air Pollutants ("NESHAP") and ***admits that ethylene oxide emissions from the Willowbrook facility meet those requirements*** (in truth, the ethylene oxide emissions from the Willowbrook facility are actually considerably ***lower*** than are required by the NESHAP, but that fact is nowhere to be found in the Seal Order). Thus, when the Seal Order claims that there is "an imminent and substantial endangerment to public health or welfare" (*id.* at ¶ 18), it is making an assertion out of whole cloth.

This Court should immediately issue a temporary restraining order and/or a preliminary injunction barring enforcement of the Seal Order. There are two clear, independent grounds for such a ruling: (1) violation of Sterigenics' due process rights; and (2) as an award of the "immediate injunctive relief" expressly authorized under 415 ILCS 5/34(d). Such a ruling would allow the immediate resumption of the life-saving process of ethylene oxide sterilization at the Willowbrook facility.

FACTUAL BACKGROUND

A. Sterigenics and Sterilization Using Ethylene Oxide.

Sterigenics is a leading provider of high quality sterilization services. Sterigenics sterilizes medical devices, medical equipment, and surgical kits for healthcare products companies. Ethylene oxide is absolutely critical to the healthcare industry; it is used to sterilize over 50% of the medical devices and nearly 90% of the surgical kits used today. (Declaration of Kathleen Hoffman ("Hoffman Decl.") ¶¶ 2, 5 (attached as Ex. B).)

In basic terms, ethylene oxide sterilization involves placing a product in a sealed chamber, which is then filled with ethylene oxide for long enough for ethylene oxide to penetrate the product and eliminate any contaminating microbes. (*Id.* ¶ 2.) The ethylene oxide is then removed, and the product is either returned to the customer or shipped to an end user, such as a hospital. (*Id.*) The Willowbrook facility is particularly important, because it represents 4% of the national ethylene oxide sterilization capacity, has 18 sterilization chambers of various sizes, and can handle a broad range of devices. (Declaration of Philip Macnabb ("Macnabb Decl.) ¶ 6 (attached as Ex. C); Hoffman Decl. ¶ 2.)

Ethylene oxide is both ubiquitous and essential. It is pervasive in the atmosphere, arising from natural sources, everyday activities, and commercial industries. Natural sources of ethylene oxide include plants, microbes, and ripening fruits. (Hoffman Decl. ¶ 10.) Ethylene

oxide is produced by the human body as part of its normal metabolic process.[1] (*Id.*) Everyday sources of ethylene oxide include cigarette smoke and auto exhaust emissions.[2] (*Id.*) Commercial sources of ethylene oxide include chemical manufacturers, hospitals, and medical sterilization facilities near where people work or live. (*Id.* ¶ 11.) In fact, there are more than a dozen medical facilities located in DuPage and Cook counties (***none*** of which have been subject to IEPA seal orders) that use ethylene oxide to sterilize medical products. (*Id.* ¶ 12.) As a result of these natural and other sources, there is a general background level of ethylene oxide in the air. USEPA has recently recognized the existence of background ambient levels of ethylene oxide found in the environment.[3] (*Id.* ¶ 11.)

B. Ethylene Oxide Storage Containers.

Ethylene oxide is delivered to and stored at the Willowbrook facility in specialized containers. Those containers are highly regulated and must meet strict requirements promulgated by the U.S. Department of Transportation as set forth in 49 C.F.R. 173.323. (Affidavit of David F. Ludwig ("Ludwig Aff.") ¶ 3 (attached as Ex. D).) Specifically, Sterigenics' ethylene oxide supplier ships ethylene oxide in 1A1 steel drums. (*Id.* ¶ 4.) These 1A1 steel drums are:

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[1] *Sterigenics Willowbrook Facility: Frequent Questions,* U.S. ENVT'L PROTECTION AGENCY, https://www.epa.gov/il/sterigenics-willowbrook-facility-frequent-questions (last visited Feb. 15, 2019) ("[O]ur bodies produce ethylene oxide when metabolizing ethylene, which is produced naturally in the body.").

[2] *Tox Town: Ethylene Oxide,* U.S. NATIONAL LIBRARY OF MEDICINE, https://toxtown.nlm.nih.gov/chemicals-and-contaminants/ethylene-oxide (last visited Feb. 15, 2019) (["Ethylene oxide] is emitted from fossil fuels such as petroleum, natural gas, and coal, and from tobacco products.")

[3] *See EPA in Illinois, Sterigenics Willowbrook Facility: Frequent Questions,* U.S. ENVT'L PROTECTION AGENCY, https://www.epa.gov/il/sterigenics-willowbrook-facility-frequent-questions (discussing background levels of ethylene oxide in response to the question "[w]hy can't you tell me my risk from these monitoring results?") (last visited Feb. 11, 2019); *Webinar: Ethylene Oxide Willowbrook Data,* U.S. ENVT'L PROTECTION AGENCY, *available at* https://www.youtube.com/watch?v=0j_O_GJbchc (last visited Feb. 11, 2019) (providing varying potential background levels of ethylene oxide).

> lagged of all welded construction with the inner shell having a minimum thickness of 1.7 mm (0.068 inches) and the outer shell having a minimum thickness of 2.4 mm (0.095 inches). . . . [L]agging must be of sufficient thickness so that the drum, when filled with ethylene oxide and equipped with the required pressure relief device, will not rupture when exposed to fire. . . . Before each refilling, ***each drum is tested for leakage*** at no less than 103 kPa (15 psig) pressure.

(*Id.* ¶¶ 4–5; 49 C.F.R. § 173.323(b)(3)). Before these drums are off-loaded at the Willowbrook facility, they are checked for leaks. The facility rejects any drum that it determines might be leaking, and that drum is returned to the supplier. (Hoffman. Decl. ¶ 16.) The drums are kept in a designated storage area until needed for the sterilization process. (*Id.*) To use the drums, "facility personnel connect the drum to the piping system that feeds the sterilization chambers. Facility personnel are trained in the connection process, which is designed to create a secure connection between the drum and piping system with no emissions from the drum or the connection." (*Id.* ¶ 17.) There are ethylene oxide monitoring ports in the drum storage area to detect any ethylene oxide leakage from the drums. (*Id.*)

C. FDA Requirements.

The Food and Drug Administration ("FDA") regulates ethylene oxide sterilization and, as part of its work, inspects sterilization facilities, including the Willowbrook facility. (*Id.* ¶ 4.) Ethylene oxide sterilization is the ***only*** practical, FDA-approved method for sterilizing a wide variety of medical devices. (*Id.* ¶ 6; September 24, 2018 Letter from AdvaMed to Andrew Wheeler, U.S. EPA ("AdvaMed Letter") (attached as Ex. E).)

FDA requires that medical devices and equipment be sterilized pursuant to exacting protocols which are rigorously tested and validated. (Hoffman Decl. ¶ 8.) There are detailed procedures for the equipment, method, and steps used for the ethylene oxide sterilization of each type of each type of medical device or surgical kit processed at the Willowbrook facility, and the

equipment at the facility is continually checked and calibrated to ensure adherence to those procedures. (*Id.*) The FDA-required validation and calibration process is expensive and can take anywhere from four and six months. (*Id.* ¶ 9.) This process is tied not only to the specific sterilization company, ***but also to the specific chamber***. If a chamber is unavailable, a product that is calibrated and validated for that chamber cannot simply be switched to another chamber, whether at the same or a different facility. (*Id.* at ¶ 9; *see also* Macnabb Decl. ¶ 6.) Similarly, a customer cannot simply switch to another facility; it must redo the entire months-long FDA validation process described above. (Mcnabb Decl. ¶ 6.; Illinois Senate Hearing, IAG Action Dkt. 1-7 at PageID 203–04.) As a result, "even a temporary shut-down of the Willowbrook facility would cause significant shortages in sterilized medical equipment in Illinois and throughout the country." (Hoffman Decl. ¶ 9; *see also* Illinois Senate Hearing, IAG Action Dkt. 1-7 at PageID 204; Macnabb Decl. ¶ 7.)

D. Regulatory Compliance for Ethylene Oxide Emissions.

The Willowbrook facility's ethylene oxide emissions are highly regulated at the federal and state levels. Specifically, the Clean Air Act NESHAP for ethylene oxide sets a 99% control requirement. 40 C.F.R. Part 63, Subpart O. The Willowbrook facility operates pursuant to an IEPA-issued Clean Air Act Permit Program ("CAAPP") permit, which incorporates the NESHAP standard. (IAG Action Dkt. 1-1 at PageID 91, 93.) The permit also sets specific limits on how much ethylene oxide can be used and emitted annually at the Willowbrook facility. (*Id.* at Page ID 93, 96.) Sterigenics cannot even install new equipment to ***reduce*** emissions of ethylene oxide without first obtaining regulatory authorization. (*Id.* at Page ID 95.) Finally, both state and federal governments have been aware of the Willowbrook facility's ethylene oxide emissions for decades via Sterigenics' Annual Emission Reports. (*Id.* at Page ID 93–94.)

IEPA has ***expressly authorized*** the Willowbrook facility's ethylene oxide emissions for years. IEPA has issued multiple permits to Sterigenics since 2006.[4] (*Id.* at Page ID 91.) It also issued permits to prior owners of the Willowbrook facility, thus the Willowbrook facility has been subject to an IEPA-issued operating permit for more than three decades. (IAG Action Dkt. 35-1.)

E. The IRIS Assessment and the ATSDR Report.

On August 21, 2018, ATSDR released a Letter Health Consultation Report ("ATSDR report") that purported to address whether ethylene oxide from the Willowbrook facility posed a public health problem for people living and working in Willowbrook. The ATSDR report used the USEPA's Integrated Risk Information System ("IRIS") and air monitoring data collected by USEPA Region 5 on May 16 and May 17, 2018, to conclude that: "If measured and modeled data represent typical [ethylene oxide] ambient concentrations in ambient air, an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility."[5] However, the USEPA monitoring data, the IRIS risk assessment, and the methodology employed by the ATSDR have since been proven faulty, calling into question the validity of the ATSDR report itself.

1. Flaws Revealed in the IRIS Risk Assessment

[4] On January 30, 2006, IEPA issued modified CAAPP Permit No. 95120085 to Sterigenics for the Willowbrook facility. (IAG Action, Dkt. 1-1 at Page ID 91.) On June 8, 2016, IEPA issued renewal CAAPP Permit No. 95120085 to Sterigenics for the Willowbrook facility, which, like the initial permit, includes the NESHAP for ethylene oxide emission from sterilization facilities. (*Id.* at Page ID 93.) On June 26, 2018, IEPA issued Sterigenics Permit No. 18060020 to duct the emissions of ethylene oxide from the back vent valves to existing pollution control devices. (*Id.*at Page ID 95.)

[5] See *Evaluation of Potential Health Impacts from Ethylene Oxide Emissions*, U.S. DEP'T OF HEALTH & HUM. SERVS. 1 (August 21, 2018), https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc-508.pdf

In December 2016, IRIS changed the inhalation unit risk for ethylene oxide from 0.0001 per microgram per cubic meter (µg/m^3) to 0.003 per µg/m^3, which represents IRIS's estimate that ethylene oxide was 30 times more potent as a carcinogen than previously estimated.[6] Significantly, IRIS does not promulgate regulations, and IRIS's assessments do not have the force of law. Instead, IRIS gathers information that USEPA staff may consider and analyze in risk assessments, decision-making and regulatory activities.[7] As USEPA's website clarifies, "[i]n general IRIS values cannot be validly used to accurately predict the incidence of human disease or the type of effects that chemical exposures have on humans."[8]

As explained by Dr. Kenneth Mundt, IRIS's inhalation unit risk regarding ethylene oxide ***does not comport with the epidemiological reality***. (Declaration of Kenneth A. Mundt ("Mundt Decl.") ¶ 11 (attached as Ex. F).) In particular, ambient air testing conducted in October 2018 shows that the average background levels of ethylene oxide in the air in the greater Chicago area and suburbs are 0.280 µg/m^3. Similarly, ambient air testing conducted in November 2018 shows that average background levels of ethylene oxide in the air in the Chicago area at 0.210 µg/m^3.[9] There are numerous sources of ethylene oxide contributing to its ubiquity in the environment. For example, auto products, cleaners, home maintenance products, and cigarettes all contribute to ethylene oxide levels in the environment. Indeed, USEPA has noted that the levels of ethylene oxide in the ambient air test results reflect

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[6] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*, INTEGRATED RISK INFORMATION SYSTEM (IRIS), at 1-7 (Dec. 2016), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.
[7] *See Integrated Risk Information System (IRIS): Overview*, U.S. EPA, https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2776.
[8] *See id.*
[9] *Update on Chicago Area Background Levels of EO*, STERIGENICS, https://www.sterigenicswillowbrook.com/new-page-1 (last visited February 18, 2019).

"extremely low levels in the atmosphere . . . part per billion and part per trillion numbers and it doesn't take very much of this material or any material to cause those kinds of levels in the air." (*Id.* ¶ 13.) In addition, IRIS applied an inappropriate statistical model to reach its conclusions. (*Id.* ¶¶ 15–16.)

Based on IRIS's faulty underpinnings, the USEPA's National Air Toxics Assessment ("NATA") office then used the IRIS assessment to identify Willowbrook as having several census tracts which may have an elevated risk of cancer. (*Id.* ¶ 18.) However, this was based on the flawed IRIS assessment. (*Id.* ¶ 19.)

Neither NATA nor IRIS are regulations; they are nothing more than analyses that USEPA or other agencies may find useful when setting priorities or writing regulations.[10] Thus, the Seal Order, is ***not based on a violation of any regulation***.

2. Faulty USEPA Data

Three months after the ATSDR report's release, USEPA was forced to admit that there was "an issue with the way ethylene oxide has been measured" such that "monitors may have reported higher ambient levels of ethylene oxide than actually exist" due to Trans-2-butene potentially being incorrectly identified as ethylene oxide.[11] USEPA further admitted that, due to this issue, "the results of air quality monitoring conducted prior to October 2018 may have shown higher concentrations of ethylene oxide than were actually in the air. ***This includes air quality monitoring that U.S. EPA's Region 5 conducted in mid-***

[10] *Agency for Toxic Substances and Disease Registry (ATSDR) Statement about the Letter Health Consultation*, ATSDR, https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_ATSDR_Public_Statement-508.pdf (last visited Feb. 18, 2019) (ATSDR noted that the ATSDR report was intended to "inform and support . . . regulatory decisions.").

[11] *EPA in Illinois: Sterigenics Willowbrook Facility – Latest Update: Update November 21, 2018*, U.S. ENVT'L PROTECTION AGENCY, https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update#20181123 (last visited February 17, 2019).

May 2018 in Willowbrook, Illinois" which was relied upon in the ATSDR report.[12] The Seal Order, nevertheless, is based on this faulty data.

3. ATSDR's Unreliable Methodology

ATSDR's methods were unreliable and were highly biased toward a nonsensical worst-case scenario. ATSDR relied upon the highest concentration of ethylene oxide detected in the residential area samples, which were collected under non-representative weather conditions.[13] As Willowbrook Mayor Frank Trilla stated during a town hall meeting on August 29, 2018, the ATSDR "took the [worst] case scenario, multiplied it by 30 years, 250 days a year, 24 hours exposure . . . and the wind had to be identical for the entire 30 years — under those circumstances 6.4 people out of 1,000 might be affected by this." (IAG Action Dkt. 1-5 at 8:20.) ATSDR eventually admitted that it "biased [the tests] on purpose to try to capture what might be the worst exposure in the community when they're downwind from the facility." (*Id.* at 9:55.) An ATSDR representative also admitted, "I don't know if anyone's home 24 hours a day, 7 days a week for an entire year for 33 years. Which is what we assumed." (*Id.* at 10:22.)

In addition, of the 39 samples, total, that USEPA obtained, ATSDR selected only two, representing the highest maximum concentrations obtained during a 12-hour sampling period, for purposes of estimating exposure to ethylene oxide.[14] ATSDR also did not account for a subsequent, voluntary upgrade to the Willowbrook facility, which reduced emissions ***below the already approved and compliant levels***. (Hoffman Decl. ¶ 13–14.) Indeed, on August 29, 2018, then IEPA Director Alec Messina admitted that the Willowbrook facility is "in compliance with

[12] *Id.* (emphasis supplied).
[13] See *Evaluation of Potential Health Impacts from Ethylene Oxide Emissions*, U.S. DEP'T OF HEALTH & HUM. SERVS. at 11 (August 21, 2018), https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc508.pdf
[14] *Id.* at 5–7.

all the federal regulations including the emissions standards for ethylene oxide." (IAG Action Dkt. 1-5 at 3:46.)

F. Following the Release of the ATSDR Report, ATSDR, IEPA and USEPA Acknowledged There Is No Immediate Health Threat.

Less than a week after the release of its report, ATSDR acknowledged that its report is "not one that indicated immediate health threat or that there was an emergency situation." (*Id*. at 0:42.) As ATSDR explained, its "communication strategy fell through [and] did not allow us to really put this into context." (*Id.*) ATSDR also issued a public statement clarifying that the Willowbrook facility's ethylene oxide emissions "***are not an immediate threat to public health and are not considered to be an emergency situation***."[15]

On September 27, 2018, USEPA sent letters to several Illinois elected officials specifically noting that "the air concentrations of ethylene oxide are not high enough to cause immediate harm to health for the people in and around Willowbrook." (*Id*. IAG Action Dkt. 1-6.) Further, USEPA noted that "[e]arly indications from the post-control stack testing suggest that emissions have indeed been significantly reduced." (*Id.*) USEPA concluded by noting that ATSDR's overstated risk assessment was based on "someone who is continuously exposed to [ethylene oxide] for 24 hours per day over 70 years." (*Id.*)

The purpose of ATSDR's report is to "inform and support . . . ***regulatory*** decisions."[16] IEPA's deprivation of Sterigenics' lawful and permitted operation of its facility without due process is thus rooted in faulty, misapplied data and a thoroughly compromised and misused ATSDR report.

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[15] *Agency for Toxic Substances and Disease Registry (ATSDR) Statement about the Letter Health Consultation*, ATSDR, https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_ATSDR_Public_Statement-508.pdf (last visited Feb. 18, 2019).

[16] *Id.*

G. The State's Complaint and Subsequent Filings.

On October 30, 2018, and at the request of IEPA, the State filed the IAG Action, making a claim against Sterigenics for "Causing, Threatening or Allowing Air Pollution" and seeking as relief "a preliminary and, after trial, permanent injunction." (*Id.* IAG Action Dkt. 1-1.) However, the State has ***never*** moved for a preliminary injunction. On December 5, 2018, Sterigenics timely removed this case to federal court based on federal-question jurisdiction. *(Id.* IAG Action Dkt. 1.) The parties subsequently briefed the State's Motion to Remand. (*Id*. IAG Action Dkt. 28, 35, 36.) The State then filed a Motion to Expedite the Court's decision on remand (*Id*. IAG Action Dkt. 37), which the Court granted to the extent it "acknowledge[d] the concerns expressed by the parties and will issue a ruling on the motion for remand as soon as practicable." (*Id*. IAG Action Dkt. 43.) The Court concluded on Friday, February 15, 2019, that supplemental briefing regarding the Motion to Remand was required. (*Id.* IAG Action Dkt. 44.) That evening, IEPA issued its Seal Order—thus abrogating Sterigenics' due process rights and circumventing Sterigenics' opportunity to respond to and the Court's authority to rule on the State's still-unfiled motion for a preliminary injunction.

H. The Seal Order.

The operative language of the Seal Order applies to "All storage containers of ethylene oxide." However, there is no allegation that ethylene oxide emissions are caused by leaks from the ethylene oxide storage containers, nor could there be.

The Seal Order asserts that Sterigenics' operations are near "homes, schools, parks, government buildings, and businesses." (S.O. ¶ 9). But, it neglects to mention that Sterigenics is also nestled in-between two major highways and businesses such as Viscosity

Oil Co., Lyons Truck Sales, and Chicago Hardwood Flooring. This is significant for two reasons. First, ATSDR's conclusions assume that people are exposed to ethylene oxide from Sterigenics 24 hours a day, seven days a week, for 30 consecutive years. (Mundt Decl. ¶ 19). That assumption is clearly inappropriate for business and commercial locations. Second, auto exhaust is a source of ethylene oxide (Hoffman Decl. ¶ 10), which can be expected in abundance where Sterigenics is located.

Second, the Seal Order vaguely asserts that air sampling conducted by USEPA and the Village of Willowbrook in November and December of 2018 found "outdoor ambient levels of ethylene oxide in commercial and residential areas as high or higher than the levels used by ATSDR." (S.O. ¶ 14.) However, of course, the ATSDR report is not a regulation. USEPA, which IEPA relies on with respect to air quality standards,[17] itself noted on February 5, 2019, that "monitoring information about ethylene oxide in Willowbrook remains limited" and "[i]t ***remains premature to draw conclusions about long-term health risks from the data***."[18]

Third, the Seal Order admits Sterigenics' compliance with the NESHAP for ethylene oxide (S.O. ¶ 17) but implies that it is insufficient because it was "promulgated . . . well before the recognition of ethylene oxide as a human carcinogen." (*Id.* ¶ 15.) However, the Seal Order contradicts itself, stating that "[f]rom 1985 to 2016 [USEPA] categorized ethylene oxide as 'probably carcinogenic.'" Further, USEPA reconsidered the NESHAP standard for ethylene oxide as recently as 2006. 71 Fed. Reg. 17712 (Apr. 7, 2006).

[17] *See* IAG Action, Dkt. 35-2 at Page ID 529.
[18] *EPA in Illinois: Sterigenics Willowbrook Facility – Latest Update: Update February 8, 2019*, U.S. ENVT'L PROTECTION AGENCY, https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update#20181123 (last visited February 17, 2019).

Finally, the Seal Order asserts that the 2016 IRIS Evaluation recognized "an increased cancer incidence and mortality of breast and lymphohematopoietic system cancers . . . in workers at sterilization operations using ethylene oxide." (S.O. ¶ 6.) But the studies on which IRIS relied specifically found that there is no overall increase in breast cancer among the women in the study; the only increased risk for breast cancer was found among women with the highest cumulative exposures to ethylene oxide. (Mundt Decl. ¶ 16.) In other words, only those women whose accumulated exposure was the highest in the studied population risked developing breast cancer. Analysis of the cohort as a whole revealed no statistically significant relationship between ethylene oxide and cancer. (*Id.*) Not only does IEPA overstate the cancer risk, but IRIS itself recognized that the studies it relied on were limited, noting that "[The authors] suggest that their findings are not conclusive of a causal association between [ethylene oxide] exposure and breast cancer incidence due to inconsistencies in exposure-response trends, possible biases due to nonresponse, and an incomplete cancer ascertainment." (*Id.*) Even more egregious is IEPA's claim regarding lymphohematopoietic system cancers, as the study of sterilization workers relied on by IRIS "showed no statistically significant increase in mortality for lymphohematopoietic cancers overall or for specific categories of Hodgkin's lymphoma, non-Hodgkin's lymphoma, myeloma, and leukemia." (*Id.* ¶ 20.) Even IRIS admits that the "magnitude of the effect [of ethylene oxide exposure] was not large."[19]

ARGUMENT

[19] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*, Integrated Risk Information System (IRIS), at 3-13 (Dec. 2016), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.

I. A TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, OR PERMANENT INJUNCTION UNSEALING THE WILLOWBROOK FACILITY IS PROPER.

To obtain a temporary restraining order or preliminary injunction "the moving party must demonstrate a reasonable likelihood of success on the merits, no adequate remedy at law, and irreparable harm absent the injunction." *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't Health*, 699 F.3d 962, 972 (7th Cir. 2012) (weighing factors using a "sliding scale"); *see also YourNetDating, Inc. v. Mitchell*, 88 F. Supp. 2d 870, 871 (N.D. Ill. 2000) (holding that the standards for "whether a TRO is appropriate are analogous to the standards applicable when determining whether preliminary injunctive relief is appropriate"); *City of Chicago v. Sessions*, 321 F. Supp. 3d 855, 876 (N.D. Ill. 2018) (similar). Where these factors are met, courts consider the balance of harms and the public interest. For the balance of harms, courts weigh irreparable harm to the movant "against any irreparable harm the non-moving party would suffer" if the injunction issues. *Girl Scouts of Manitou Council, Inc. v. Girl Scouts of U.S., Inc.*, 549 F.3d 1079, 1086 (7th Cir. 2008). Courts then assess the overall "balance of equities and the public interest in determining whether to grant a preliminary injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 26 (2008).

Based on these well-established factors, Sterigenics is entitled to entry of a temporary restraining order and/or preliminary injunction barring enforcement of the Seal Order.

A. Sterigenics Has A Strong Likelihood of Success On The Merits.

To meet the threshold requirement of "likelihood of success on the merits," Sterigenics "need only demonstrate a better than negligible chance of succeeding" on one of its claims. *Farnam v. Walker*, 593 F. Supp. 2d 1000, 1014 (C.D. Ill. 2009). This requirement "is a low one." *Sofinet v. I.N.S.*, 188 F.3d 703, 707 (7th Cir. 1999). Sterigenics easily meets this requirement.

1. Sterigenics Is Likely to Succeed on Its Due Process Claim.

The Seal Order, without notice or hearing or any process whatsoever, deprives Sterigenics of the right to use its property to lawfully conduct its business pursuant to the CAAPP permit that IEPA itself issued. This is a straightforward violation of Sterigenics' due process rights—and indeed a blatant end run around the regulatory and judicial processes that IEPA is obligated to follow, and through which Sterigenics would have the opportunity to be heard that the United States Constitution requires.

Sterigenics' right to operate the Willowbrook facility pursuant to the CAAPP permit issued by IEPA is a property right subject to due process requirements. *See, e.g.*, *Easter House v. Felder*, 910 F.2d 1387, 1395 (7th Cir. 1990). The "fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (internal citations omitted). An opportunity to be heard must be granted ***before*** any initial deprivation of property takes place except "in limited cases demanding prompt action." *Fed. Deposit Ins. Corp. v. Mallen*, 486 U.S. 230, 240 (1988). "[A]bsent 'the necessity of quick action by the State or the impracticality of providing any predeprivation process,' a post-deprivation hearing here would be constitutionally inadequate." *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 435 (quoting *Parratt v. Taylor*, 451 U.S. 527, 539 (1981)); *see also Gates v. City of Chicago*, 623 F.3d 389, 401 (7th Cir. 2010) (the Due Process Clause of the United States Constitution requires that any state action that deprives an individual of a property or liberty interest "be preceded by notice and opportunity for hearing appropriate to the nature of the case") (quoting *Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 313 (1950)).

IEPA's decision to forgo all predeprivation process here cannot be reconciled with the Due Process Clause. It is undisputed—and conceded by the Seal Order (¶¶ 15–17)—that

Sterigenics has throughout this period been operating the Willowbrook facility ***in the manner that IEPA itself has licensed***. Nonetheless, the Seal Order applies to "[a]ll storage containers of ethylene oxide" purportedly pursuant to the "imminent and substantial endangerment provision" of Section 34(b) of the Illinois Environmental Protection Act. ***Nowhere*** in the Seal Order does IEPA explain how the "storage containers of ethylene oxide" are causing an "imminent and substantial endangerment." Instead, the sole basis the Seal Order articulates for depriving Sterigenics of the use of its property that IEPA itself has licensed is the ATSDR report on ethylene oxide issued some six months ago. (S.O. ¶ 12.) However, the ATSDR report did not change the law—it neither changed the NESHAP standard adopted by the USEPA nor rescinded the CAAPP permit issued by the IEPA incorporating the NESHAP standard.

Tellingly, IEPA has made no effort through the regulatory process to modify its requirements as to ethylene oxide. If IEPA believes Sterigenics' ***concededly lawful*** actions threaten the public health, IEPA's recourse is to seek to amend the laws or regulations with which Sterigenics is complying through the legislative or regulatory process. *See Logan*, 455 U.S. at 432–33 (general scope of property rights may be modified through the regulatory or legislative process consistent with due process requirements). Yet, despite having the information included in the ATSDR report for nearly six months, IEPA has taken ***no action*** whatsoever to modify its applicable regulations or the CAAPP permit that it granted to Sterigenics and under which Sterigenics lawfully operates.

IEPA has also issued its Seal Order without bothering to pursue judicial approval in the ***already pending*** lawsuit filed by the State at its request. Instead of seeking the preliminary injunction expressly prayed for in the State's Complaint, IEPA and Kim have simply declared a non-existent emergency and shut down the Willowbrook facility. In short, through this Seal

Order, IEPA and Kim are improperly seeking to circumvent both the regulatory and judicial processes.

Nor can postdeprivation process satisfy constitutional requirements in these circumstances. *See Logan*, 455 U.S. at 437 (postdeprivation process is "particularly" unsuitable where it is "apt to be a lengthy and speculative process"). As detailed below, even if Sterigenics succeeds at a later point in time in having the Seal Order lifted, it will suffer permanent and irreparable harm from even a short shut-down of the facility, as will its customers. *Infra*, p. 23–24. In these circumstances, where IEPA has no meaningful interest in depriving Sterigenics of its right to conduct ***concededly lawful*** business operations without providing predeprivation process, IEPA's actions violate due process requirements. *See Mathews*, 424 U.S. at 333.

Thus, Sterigenics is entitled to immediate entry of a temporary restraining order and/or preliminary injunction.

2. Sterigenics Is Likely to Succeed on Its Claim Under Section 34(d).

Section 34(b)(2) of the Illinois Environmental Protection Act, 415 ILCS 5/34(b)(2), upon which the Seal Order relies, authorizes IEPA to issue a seal order where "an imminent and substantial endangerment to the public health or welfare or the environment exists" and provides that IEPA "may seal any equipment . . . or other facility contributing to the imminent and substantial endangerment." Section 34(d) provides that the impacted party, *i.e.* Sterigenics, may "seek immediate injunctive relief."

The Seal Order is facially deficient. Notably, the Seal Order does not even attempt to show any sort of "imminent and substantial" endangerment caused by the ethylene oxide containers. In fact, the word "container" is only mentioned once in the Seal Order—at the end, in the operative language, applying a seal to "All storage containers of ethylene oxide." (S.O. at

p. 3.) The Seal Order makes no attempt to connect the containers to its cursory and inaccurate description of the deeply flawed and non-regulatory work of IRIS and ATSDR.

Not only does the Seal Order fail to demonstrate an "imminent and substantial" danger from the storage containers, the overwhelming, indeed only, evidence is that these highly regulated containers are abundantly safe. The containers comply with applicable U.S. Department of Transportation regulations requiring that, before each drum is filled with ethylene oxide each refilling, it "***is tested for leakage*** at no less than 103 kPa (15 psig) pressure." 49 C.F.R. § 173.323(b)(3). (Ludwig Aff. ¶ 5.) Additionally, before the Willowbrook facility will allow the drum to enter the premises, each and every drum is checked for leaks, and any potentially leaking or non-complaint drums are not accepted. (Hoffman Decl. ¶ 16.) If the drums pass inspection, they are stored in a designated storage area until they are needed for the sterilization process. (*Id*.) To further ensure the safety of their employees and the community, the facility maintains ethylene oxide monitoring ports in the drum storage area and is able to detect any ethylene oxide leakage from the drums. (*Id.* ¶ 17.) Thus, not only is the Seal Order devoid of ***any*** evidence to show the ethylene oxide containers pose an imminent and substantial threat to public health and safety, but there is ample evidence demonstrating the contrary.

The use of a seal order here is completely unprecedented and unjust. The legislative history and application of seal orders makes clear that they are not intended to apply to facilities that are complying with their obligations, nor are they to be used as an end-run around the procedural requirements necessary for IEPA to issue new regulations. The "imminent and substantial endangerment" basis in Section 34 upon which IEPA issued its seal order was introduced as part of Senate Bill No. 431 in 2005, which was commonly known as the "Illinois

Removes Illegal Dumps" bill. Illinois House Transcript, 2005 Reg. Sess. No. 59. The purpose of the statute is to crack down on ***illegal dumping operations***. Illinois Senate Transcript, 2005 Reg. Sess. No. 31. Seal orders are rarely issued, and then only where there is a history of regulatory violations and/or a genuine, demonstrable threat to public health and safety.

Indeed, the only seal order that could be located via publicly available information sources was from 2006 and, unsurprisingly, addressed illegal dumping. In 2006 IEPA issued a seal order against John Tarkowski (attached as Ex. G) because ***he ran an illegal dump on his property for decades***. *See Tarkowski v. Cty. of Lake*, No. 94 C 3590, 1994 WL 405991, at *2–3 (N.D. Ill. July 29, 1994). Before issuance of the seal order, IEPA inspected the property multiple times and ultimately obtained a court order against Tarkowski, which required him to clean the property. (*Id.* ¶ 4.) Tarkowski ignored this order (*id.* ¶ 6), after which IEPA sought and obtained a seal order due to the risk of West Nile Virus associated with tires on the property (*id.* ¶ 7). The lawful use of ethylene oxide at the Willowbrook facility is incomparable to the facts underlying the Tarkowski seal order. Sterigenics is not illegally dumping waste, and is actually in compliance with all emissions regulatory requirements. Nor is the Seal Order connected to any investigation confirming the existence of conditions leading to imminent and substantial endangerment. The rarity with which seal orders have been issued, and the extreme facts underlying the Tarkowski order, make clear that the Seal Order issued against Sterigenics' ethylene oxide storage tanks is baseless, arbitrary, capricious and unreasonable.

Unlike in the Tarkowski matter, Sterigenics is ***not*** in violation of any law or regulation. Sterigenics' ethylene oxide emissions are all IEPA-approved, and USEPA and IEPA have both acknowledged there is no imminent threat to health or safety.[20] The Seal Order is a travesty, and

[20] Between November 2018 and February 2019, USEPA, the Village of Willowbrook, and the neighboring Village of Burr Ridge have sampled the air in the general vicinity of the

Sterigenics has easily met the requirement that it establish its likelihood of success on the merits of its Section 34(d) claim.

B. The Public Interest Favors a TRO, Preliminary Injunction, or Permanent Injunction.

The usual order would be next to address the lack of an adequate remedy at law and irreparable harm, but the public interest is so important – and has been so completely misrepresented in nonstop, inaccurate press coverage of this situation – that it cannot wait.

To begin with, in shutting down the Willowbrook facility, the Seal Order itself risks imminently and substantially endangering the public health and welfare. Each day it is in operation, the Willowbrook facility sterilizes approximately 1,000 cardiac devices used in heart surgery, 1,000 knee implants, 1,500 surgical procedure kits, 16,000 catheters, 11,000 syringes for injections used in radiology diagnosis, and thousands of diabetes monitoring and care kits, renal care products, neurosurgical devices, and respiratory care products. (Macnabb Decl. ¶ 2.)

Willowbrook facility, with results reported for approximately 165 samples taken in November and December. (USEPA results are available athttps://www.epa.gov/il/outdoor-air-monitoring-data-willowbrook-community; the Village of Willowbrook report is available at http://www.willowbrookil.org/DocumentCenter/View/1500, and Village of Burr Ridge report is available at http://www.burr-ridge.gov/wp-content/uploads/sp-client-document-manager/3/2018-12-07-website-post-sterigenics-ambient-air-testing-results.pdf.) These samples contained air concentrations of ethylene oxide ranging from non-detectable to 11.7 micrograms per cubic meter (ug/m^3), with results in residential areas mostly below 1 ug/m^3 and similar to background concentrations detected elsewhere in the Chicago area. It has been reported that, in early February, the Village of Willowbrook obtained some readings – which, on information and belief, have not been corroborated or subject to quality control – that substantially deviated from all prior testing, including the Village's own testing. But even the Seal Order prudently refrains from citing these inexplicable reports of results. This is proper, as no validation information for these results is available. In addition, the IRIS risk assessment and the ATSDR report are all focused on alleged risk from ***long-term, chronic*** exposure to ethylene oxide, and individual readings of air concentration over a 12-hour period are not relevant. All readings that any party has obtained in the vicinity of the Willowbrook facility are well below the federal regulatory limit for occupational exposure, 29 C.F.R. § 1047(c)(1) (2018) (setting permissible exposure limit at 1 part per million (or 1,830 ug/m^3), averaged over an eight hour period), and no one suggests that these detected concentrations can cause short-term adverse health effects.

By shutting down the Willowbrook facility, the Seal Order has immediately disrupted the supply of medical devices used for, *inter alia*, heart surgeries, the implantation of prosthetic devices, injections, and urinary drainage. And, the customers that rely on Sterigenics' services ***cannot*** simply turn around and find a new sterilization company. First, these customers would be limited to ethylene oxide sterilization companies, since many heat- and irradiation-sensitive devices can only be sterilized using ethylene oxide. (Illinois Senate Hearing, IAG Action Dkt. 1-7 at, PageID 201–202; AdvaMed Letter, Ex. E; MacNabb Decl. ¶ 5) Second, even if a customer is able to locate an ethylene oxide sterilization company that can accommodate its product, it would still be ***months*** before the product can be sterilized in this new chamber. (Illinois Senate Hearing, IAG Action Dkt. 1-7 at PageID 203-204; AdvaMed Letter, Ex. E.) Third, the Willowbrook facility represents about 4% of the total ethylene oxide sterilization capacity in the United States; there is simply not enough capacity available at other locations to absorb the products currently processed there. (MacNabb Decl. ¶ 6.) Fourth, hospitals and other medical service providers simply do not keep several months' supplies of medical equipment on hand – ***on-hand supplies are typically about 30 days or less***. (*Id.* ¶ 4.)

Every day the Seal Order remains in place, the supply chain will be disrupted for thousands of medical devices the Willowbrook facility would normally be sterilizing. Given the importance of the Willowbrook facility's sterilization processing, the shut-down may soon force suppliers to delay or ration deliveries and hospitals to triage procedures and to delay procedures determined to be non-critical. (*Id.*) Delaying "non-critical" procedures will, at a minimum, negatively impact the lives of those patients and their families.

The Seal Order harms the public interest. That may not be the narrative favored by many in the press or by those who, for whatever their reasons, believe it is appropriate to continue to incite fear and concern among members of the public, but it is the simple, unvarnished truth.

C. Sterigenics Will Suffer Irreparable Harm Absent Injunctive Relief.

For decades, Sterigenics has built its reputation as a reliable, safe, and innovative sterilization company. That reputation is based on the company's superior performance in its field. Shutting down the Willowbrook facility, even for a short period of time, will irreparably damage that reputation. Most notably, closing the facility for even a short period of time will cause irreparable harm to the company's customer relationships. (MacNabb Decl. ¶ 10.) As explained above, the validation and calibration processes can take anywhere from four to six months, which creates a clear gap given that health care providers generally only keep 30-days' worth of supply on hand. Plus, once those customers spend four to six months validating and calibrating their process at another facility, they may not return to Sterigenics when the Willowbrook facility reopens. What supplier of critical medical devices – or manufacturer of any kind, for that matter – would want to rely on a facility in a state where regulations can be ignored and compliant facilities can be shuttered by fiat on the whim of a public-relations-motivated decision?

In addition, Sterigenics employs 42 people in a variety of roles at the Willowbrook facility: plant managers, quality control, maintenance, customer service, operations and logistics, and training. (MacNabb Decl. ¶ 8.) Some of these employees have been working at the Willowbrook facility for decades. (*Id.*) The Seal Order, if not immediately enjoined, will result in facility-wide furloughs, in the best case, and facility-wide lay-offs, in the worst case. (*Id.*) A facility-wide lay-off would be to the irreparable detriment of Sterigenics' employees, their families, and their communities.

As noted above, a protracted shut-down would disrupt the supply of sterilized medical equipment in Illinois and elsewhere. A shut-down also causes immediate and irreparable financial harm to Sterigenics and their customers. (MacNabb Decl. ¶ 9.) Allowing IEPA to shut down properly-operating businesses which provide critical services to the public, on entirely arbitrary bases and supported by questionable science and baseless accusations would set a dangerous and confusing precedent for other law-abiding business owners and citizens of Illinois.

D. Sterigenics Has No Legal Remedy For The Improper Seal Order.

Sterigenics lacks an adequate remedy at law if the Seal Order (which has ***already*** harmed Sterigenics, its employees and its customers) is not immediately enjoined. Courts routinely hold that damage to business interests that are not readily quantifiable, such as loss of goodwill, or reputational harm, have no adequate remedy at law. *See, e.g.*, *Stuller, Inc. v. Steak N Shake Enters., Inc.*, 695 F.3d 676, 680 (7th Cir. 2012); *Gateway E. Ry. Co.*, 35 F.3d at 1140 ("We have stated that showing injury to goodwill can constitute irreparable harm that is not compensable by an award of money damages"). The only effective remedy available to Sterigenics is an immediate bar to enforcement of the Seal Order.

E. The Balance of Harm Strongly Tips In Favor of Enjoining the Seal Order and Unsealing the Containers.

The balance of harms tips decidedly in favor of awarding Sterigenics immediate injunctive relief. As long as the Willowbrook facility is shut down, Sterigenics faces mounting financial and reputational losses. Further, Sterigenics will permanently lose the benefit of using its own facility—***in the manner that IEPA itself has licensed as a permitted use of that facility***—during the period of time when the Willowbrook facility is shut down. The shut-down also puts the Willowbrook facility's employees at risk of losing pay or even a job. While

Sterigenics faces great harm absent an injunction, IEPA can show no possible harm from the requested relief.

If a no temporary restraining order or preliminary injunction is entered, but the Seal Order is ultimately found to be improper and the ethylene oxide containers are unsealed, this still will not make any affected patients whole. Patients whose procedures are delayed due to the shut-down will have no remedy for this loss time and the resulting impact on their lives.

In contrast, both USEPA and ATSDR representatives have publicly stated that there is ***no immediate harm to health or safety caused by the continued operation of the Willowbrook***.[21] For these reasons, the public interest strongly favors immediately enjoining the Seal Order, unsealing the ethylene oxide containers, and allowing Sterigenics to continue its lawful operations.

Re-opening the facility's doors will return Sterigenics to its rightful position as a long-standing, law-abiding member of the community, will restore operations, will limit the damage to customers' trust that they can use a facility in Illinois that is compliant with applicable laws and regulations, will allow dozens of workers to return to work and to earn a living and support their families, and will minimize the disruption that has been caused to the provision of medical services in Illinois and elsewhere. In contrast, declining to enter immediate injunctive relief would damage the public, Sterigenics, its employees, its customers, patients, and the provision of health and medical services in Illinois and elsewhere. Declining to enter immediate injunctive relief would also reward the disregard of due process and controlling regulations and would elevate inaccurate public statements and reporting, baseless innuendo, and blatant fear-mongering above the rule of law.

[21] *See* IAG Action, Dkt. 1-6; *id.* Dkt. 1-5 at 0:42.

CONCLUSION

For the reasons set forth above, Sterigenics respectfully requests this Court to issue a Temporary Restraining Order, Preliminary Injunction, and/or Permanent Injunction that bars enforcement of the Seal Order.

Date: February 18, 2019

Respectfully submitted,

By: */s/ Gerard D. Kelly*
Gerard D. Kelly

Maja C. Eaton
meaton@sidley.com
Gerard D. Kelly
gkelly@sidley.com
Elizabeth M. Chiarello
echiarello@sidley.com
Stephanie C. Stern
sstern@sidley.com
Kate Lambert
klambert@sidley.com
SIDLEY AUSTIN LLP
Firm ID No. 42418
One South Dearborn Street
Chicago, Illinois 60603
Telephone: (312) 853-7000
Facsimile: (312) 853-7036

Attorneys for Sterigenics U.S., LLC