IN THE SUPERIOR COURT OF NEWTON COUNTY
STATE OF GEORGIA

RICHARD E. DUNN, DIRECTOR, ENVIRONMENTAL PROTECTION DIVISION, GEORGIA DEPARTMENT OF NATURAL RESOURCES,

Plaintiff,

v.

BECTON, DICKINSON and COMPANY,

Defendant.

CIVIL ACTION FILE NO.

DEFENDANT BECTON, DICKINSON AND COMPANY'S RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER

Until it filed this lawsuit, Plaintiff Richard E. Dunn, Director, Environmental Protection Division, Georgia Department of Natural Resources ("EPD") never notified Defendant Becton, Dickinson and Company ("BD") that it was violating either its Air Quality Permit, the Georgia Air Quality Act, the federal Clean Air Act, or any other environmental statute or regulation. In fact, prior to this lawsuit, EPD repeatedly informed BD that it was in full compliance with its Permit and all applicable laws and regulations. As recently as October 2, 2019, Governor Kemp expressed appreciation for BD's efforts to provide information on the company's progress against the voluntary commitments it made on August 20, 2019. Now, in an abrupt change, EPD seeks a temporary restraining order to shut down BD's Covington facility.

In late September 2019, BD discovered an accidental release of ethylene oxide from the plant due to a valve that was found to be not fully in the closed position. After BD discovered the release, it worked quickly to rectify the issue, and a permanent solution has already been installed that removes even the possibility of future similar releases. As demanded by EPD in its Complaint,

BD has already completed installation of "blanks" on outlets for all vacuum exhaust valves at the facility. BD has also provided additional training on the proper operation of all vacuum exhaust valves at the facility. (R. Pasdon Aff., attached as Exhibit C, ¶ 9.) After discovering the release, BD voluntarily reported it to EPD and the Governor's Office within four days (even though immediate reporting was not required under Georgia's Air Quality Act or the federal Clean Air Act). BD also prepared an "incident report" detailing its efforts to quickly address the accidental release and provided it to EPD and the Governor's Office. BD has worked cooperatively and transparently with EPD to address their concerns. BD did all this without any coercion or an administrative consent order from EPD, the City of Covington, or the State of Georgia.

EPD also cites a failure to submit a permit modification to capture fugitive emissions from the Covington facility. However, in a letter to Governor Kemp on August 20, 2019, BD stated it would submit its permit application no later than October 31, 2019. In the time since BD provided the letter to Governor Kemp, neither the Governor's Office nor EPD has requested or specified an earlier submission date, so BD has not missed any deadlines with respect to submission of the permit modification.

In its Complaint, EPD suggests BD has not "cooperated" with it or the Governor's Office. The record shows otherwise. BD has been in regular weekly (and sometimes daily) communication with EPD and the Governor's Office since August 2019. BD has met in-person with EPD officials and staff five times since June 2019. (*See* Appendix 1, attached as Exhibit A.) BD has worked with EPD and the Governor's Office to address ethylene oxide emissions from its facility. (9/9/2019 Email from Broce to Woody, attached as Exhibit B-8 (Ms. Candice Broce, the Director of Communications and Deputy Executive Counsel to Governor Kemp, stated "Thank you so much for providing this update. We deeply appreciate your team keeping us appraised of

your progress.").) Contrary to EPD's assertions, BD has cooperated with EPD and the State every step along the way.

More importantly, BD has complied with all applicable laws and regulations, including the permit conditions cited by EPD in its Motion. BD far surpasses the 99% destruction efficiency requirement at the facility. On September 11-12, 2019, BD conducted a voluntary stack test through a third-party firm that found its current destruction efficiency is 99.999%. (*See* 10/1/2019 Stack Test Report, attached as Exhibit D.) In addition, BD voluntarily agreed to invest $8 million to install additional equipment that will capture fugitive emissions to an extent that is not currently in place anywhere else across the industry. (R. Pasdon Aff., attached as Exhibit C, ¶ 14.)

Despite BD's compliance with all applicable state and federal laws and regulations, EPD now seeks to shut down the Covington facility. If the facility is shuttered, it would have immediate and potentially disastrous consequences on the supply of sterilized medical devices in Georgia and throughout the United States, which would directly impact the provision of critical medical services and patient care. That impact is undisputed. (*Infra* Fact Section V.)

The United States Food and Drug Administration ("FDA") has expressed its concern on the impact of closure of the Covington facility, stating "[t]he last thing we want to see is another closure. The capacity for contract sterilizers is already strained. Our biggest concern is any strain actions might cause in terms of medical device availability." (Email from Agler to Shelkey dated July 30, 2019, attached as Exhibit E.)

The FDA is not alone in its concern. On October 23, 2019, Advanced Medical Technology Association ("AdvaMed"), an industry trade association, also commented, warning that the "attempt to shut down another medical device sterilization plant" is "alarming" and would set "Georgians and many Americans down a potentially dangerous path with serious public health

consequences." (10/23/2019 AdvaMed Statement, available at https://www.advamed.org/newsroom/press-releases/advamed-statement-bd-sterilization-plant-georgia.) Given the importance of sterilization at BD's Covington facility, closure would place "procedures for urological conditions, cardiothoracic and lung cancer surgeries, retinal detachments, and tumor ablations . . . in jeopardy." (*Id.*) In fact, given the current shortage and strain on the medical device sterilization supply chain, "[e]ven those entering intensive care units (ICUs) in the coming days could see delay in their care or lack of availability because every patient requires a catheter that must be sterilized with EtO." (*Id.*)

Additionally, customers of BD that rely on sterilized medical equipment from Covington have echoed these concerns. For example, one surgeon in southwest Georgia believes a shutdown of the Covington facility would make it difficult to obtain necessary medical devices and would put his patients at risk. (J. Morgan, III, M.D. Aff., attached as Exhibit F.) It is imperative this facility stays open so that patients across Georgia and throughout the country continue to receive the life-saving medical equipment they need.

This Court must examine the evidence—or lack thereof—provided by EPD in support of its Motion seeking to shut down the Covington facility against the undisputed evidence attached to this brief showing BD's record of compliance and cooperation with EPD and State officials, and the serious and immediate risks that closure would have on Georgia patients. As discussed more fully below, EPD is not entitled to an injunction under O.C.G.A. § 12-9-12. BD respectfully requests the Court deny EPD's Motion for a Temporary Restraining Order.

FACTUAL BACKGROUND

I. BD has Safely Operated the Covington Facility Since 1991 and Is in Full Compliance with Its Permit and State and Federal Law.

A. The Covington Facility Has Safely Used Ethylene Oxide since It Opened in 1991.

EPD states that BD has or may engage in unlawful activity at its medical device sterilization facility in Covington, Georgia. This is not true. BD has operated in Covington, Georgia since 1967 and has operated the current Covington facility since it opened in 1991. The Covington facility, like many other facilities, uses ethylene oxide in its medical device sterilization process.

BD is a state-of-the-art facility that employs best available technology to reduce its ethylene oxide emissions. BD's Permit and applicable federal law both require it to operate at a 99% destruction efficiency for ethylene oxide emissions. BD exceeds this standard, operating at a 99.999% destruction efficiency, which is far better than the limits imposed by state and federal law. (*See* 10/1/2019 Stack Test Report, attached as Exhibit D.)

B. Use of Ethylene Oxide Is Necessary for Sterilization of Millions of Medical Devices Each Year.

According to industry statistics, out of more than 40 billion medical devices sterilized annually, approximately 50% of those devices are sterilized with ethylene oxide. (Health Industry Distributors Association Statement, attached as Exhibit G, at 1.) Due to "material sensitivities," ethylene oxide "is the only option for sterilizing a large number of life-saving and life-enhancing devices, primarily those made of plastics or containing electronics, that cannot tolerate exposure to the extreme temperatures, radiation and moisture present in other sterilization methods." (*Id.*; *see also* Johann Fernando Affidavit, attached as Exhibit H, ¶ 3.) "Given the sensitive nature of the devices and the sterilization involved, the entire process is regulated by the [United States Food

and Drug Administration] FDA – where the use of EtO has been validated as a vital sterilization process." (HIDA Statement at 1.) "Most devices sterilized with EtO have no acceptable alternative, putting the supply chain at significant risk without this vital mode of sterilization." (*Id.* at 2.)

C. EPD Has Repeatedly Praised BD for Its Compliance with its Permit and All Applicable State and Federal Rules and Regulations.

BD has a strong history of compliance at its Covington facility. In fact, EPD has stated on numerous occasions that BD is in full compliance with its Permit and applicable state and federal laws and regulations:

- On July 25, 2019, EPD issued a press release regarding ethylene oxide and stated BD is "in compliance with current federal requirements for control of ethylene oxide emissions." (7/25/2019 EPD Press Release, available at https://epd.georgia.gov/press-releases/2019-07-25/statement-georgia-environmental-protection-division-regarding-ethylene.)
- On August 5, 2019 at a Covington City Council meeting, EPD verbally stated that BD was in full compliance with state and federal law. (Audio available at 27:39, https://vimeo.com/352996541.)
- On August 16, 2019, EPD again stated that BD is "operating in compliance with current requirements." (8/16/2019 Press Release, available at https://epd.georgia.gov/press-releases/2019-08-16/georgia-epd-monitor-air-quality-covington-and-smyrna-ethylene-oxide-0.)
- On August 20, 2019, at the Covington City Council meeting, EPD again verbally stated that BD was complying with its Permit. (Audio available at 48:13, (https://www.youtube.com/watch?v=qbzgoHo9N0I&feature=youtu.be&fbclid=IwAR2lWtJYj3fowV-4LOotL5_1CwJ1rX03VnVubcUFVj6n-gb5bWBDMhO4Ra4.)

D. An Accidental Release of Ethylene Oxide Occurred in September 2019, and BD Voluntarily Reported It to EPD.

At its Covington facility, BD has implemented a comprehensive system to routinely check and analyze the air within the plant for the presence of ethylene oxide. (Affidavit of R. Pasdon, attached as Exhibit C, ¶ 3.) On September 15, 2019, the technical team at BD began observing elevated ethylene oxide levels as reported on the Ambient Air Monitoring System. (*Id.*, ¶ 4.) After

significant investigations, BD determined that a vacuum exhaust valve had been closed in a partially open position. (*Id.*) Upon discovery, BD immediately closed the valve completely and confirmed the valve was properly closed. (*Id.*)

For the next several days, BD fully investigated the cause and extent of the release. On September 25, 2019, BD notified EPD of the valve closure problem and the company's initial assessment of the quantity of ethylene oxide that may have been released. (*Id.*, ¶ 5.) Subsequently, BD submitted a written report with additional information. (*Id.*) On September 27, 2019, BD informed EPD and the Governor's Office in writing that a no more than 54.5-pound unintended and accidental release of ethylene oxide had occurred over eight days from September 15, 2019 through September 22, 2019. (*Id.*, ¶ 6.)

E. BD Has Already Implemented the Corrective Measures EPD Requests in Its Complaint.

BD's September 27, 2019 report stated that by October 25, 2019, BD would complete corrective measures at the Covington facility to eliminate the possibility of any future releases of ethylene oxide from vacuum exhaust valves. (*Id.*) On October 22, 2019, BD completed the modifications to the vacuum exhaust valves and reported completion of those actions to EPD on October 23, 2019. (*Id.*) Additionally, on October 8, 2019, BD completed the training of all of its operators to prevent a future unintended and accidental release of ethylene oxide from the vacuum exhaust valves. (*Id.*, ¶ 9.) BD has taken all reasonable precautions to prevent fugitive emissions of ethylene oxide from its operations, processes, handling, transportation, and storage of ethylene oxide at the Covington facility. (*Id.*, ¶ 13.)

These measures are the same corrective actions that EPD seeks in its Complaint. (Compl. at 15-16.) It is worth noting that these three actions were voluntary actions that BD proposed and committed to do even before EPD filed this lawsuit. Put differently, EPD has not identified

anything that BD needs to do beyond what BD previously identified and committed to implement voluntarily.

II. BD Has Cooperated with EPD to Identify and Implement Steps to Reduce Ethylene Oxide Emissions at Its Covington Facility.

EPD repeatedly states that BD has not been a "cooperative partner" in reducing its ethylene oxide emissions at the Covington facility. (Compl., ¶ 16; Br. at 5,7,8.) That assertion is simply not the case.

By all objective measures, BD's cooperation with EPD since this issue arose in late 2018 has been beyond reproach. Most significantly, BD agreed to EPD's core, substantive request—to lower the fugitive emissions at the Covington facility—shortly after it was made. On July 25, 2019, BD agreed to implement additional voluntary improvements to further reduce any emissions from the Covington facility. (7/25/2019 BD Press Release, available at https://www.bd.com/en-us/company/news-and-media/press-releases/july-25-2019-bd-statement-on-georgia-facilities.) On August 15, 2019, BD committed to an aggressive schedule to determine a suitable manner for controlling fugitive emissions at the Covington facility, file a permit modification to accommodate the change in operations, and procure the labor and equipment to modify the facility. Shortly thereafter, BD confirmed this commitment in an August 20, 2019 letter to Governor Kemp, while agreeing to undertake additional changes at BD's Madison facility. (8/20/2019 Letter from Khichi to Kemp, attached as Exhibit B-2.)

The only significant request from EPD that BD categorically refused was the Division's request for BD to enter a legally-ambiguous "consent order" regarding the facility upgrades. BD was in full compliance with its permit. Moreover, it was unclear what purpose such a "consent order" would serve, since any changes to the facility would still be delayed by both the administrative process needed to modify the facility's permit and the procurement process needed

to design the upgrades, identify and obtain control equipment, and schedule a qualified contractor to install it. In short, BD takes its commitment to the protection of human health and the environment very seriously and was unwilling to create the public appearance that it had violated the law. It can hardly be faulted for doing so.

Additionally, the unambiguous record demonstrates a consistent, working relationship between EPD and BD during the entire relevant period. As explained in Appendix 1, attached as Exhibit A, BD invited EPD for a site tour, participated in regular meetings with various EPD staff and leadership, answered multiple requests for information or other assistance, reached out to EPD for regular "updates," worked with EPD in its sampling and modeling efforts, made voluntary disclosures not required by law or permit to ensure transparency, and coordinated its efforts with EPD and the City, among many other things. Frankly, except for its refusal to execute the legally dubious consent order, there is nothing to indicate that BD was in any manner uncooperative.

In short, the record lacks any evidence that BD has been unreasonable or uncooperative in its dealings with EPD. Instead, it shows that BD has worked very hard to help EPD find a reasonable, science-based solution to these issues. Far from being obstinate, BD has been compliant and accommodating of all of EPD's requests except for one.

III. BD Has Cooperated with Governor Kemp to Identify and Implement Steps to Reduce Ethylene Oxide Emissions at Its Covington Facility.

BD has similarly worked hand-in-hand with the Governor's Office to keep it apprised of BD's ongoing efforts at the Covington facility. As shown in Appendix 2, attached as Exhibit B, in early August 2019, BD reached out to Governor Brian Kemp's staff to discuss the public scrutiny of BD's use of ethylene oxide in its sterilization operations in Covington and Madison. As a result, BD met with Governor Kemp's staff and EPD leadership in Covington ahead of the Covington City Council meeting on August 5, 2019.

On August 20, 2019, BD leaders met with Governor Kemp and EPD leadership. As noted above, BD made a written commitment to the Governor at that time of the company's willingness to undertake significant voluntary improvements to further reduce its fugitive emissions as well as confirm the destruction rate of its stack emissions. While BD had reviewed the proposed improvements with EPD ahead of the meeting, it was clear that EPD had not informed the Governor or his staff of those conversations.

Following the August 20 meeting, to ensure the Governor's staff was operating with the same level of information as EPD, BD established an open line of communication with the Governor's staff and provided nearly weekly updates on the company's progress on the commitments made on August 20. BD's transparency was acknowledged positively by the Governor's staff.

Again, the undisputed evidence demonstrates BD transparency and cooperation with the Governor, State elected leaders, and EPD.

IV. There Is No Evidence of Any Imminent or Substantial Public Health Risk from Ongoing Operation of BD's Covington Facility.

EPD states that the continued operation of BD's Covington facility poses a "likelihood of harm to public health." (Br. at 5.) Again, the record does not support EPD's position.

A. Undisputed Expert Testimony Demonstrates No Public Health Risk Surrounding the Covington Facility.

In either its Complaint or its Motion, EPD presents no evidence of its assertions that medical device sterilization at BD's Covington's facility poses a public health risk. EPD provides no evidence from a toxicologist, physician, or other expert supporting its claims.

On the other hand, BD has submitted evidence from three distinguished toxicologists and physicians that have reviewed the data from the Covington facility and concluded there are no public health risks:

- Dr. Jonathan Borak, a Clinical Professor of Internal Medicine at Yale University and board-certified physician in internal medicine, preventative medicine, and toxicology, who previously served as a founding member of USEPA's National Advisory Committee to Develop Acute Exposure Guideline Levels for Hazardous Substances, testified that there was "no objective evidence in the EPD documents" that emissions from the Covington facility were "injurious." He further concluded that the "available data do not support" EPD's suggestion that certain emissions were "harmful to the public." (J. Borak Aff. Attached as Exhibit I, ¶¶ 9, 10.)
- Dr. Gail Charnley, a Massachusetts Institute of Technology toxicologist, former Director of the National Academy of Sciences Toxicology and Risk Program and Executive Director of Presidential/Congressional Commission on Risk Assessment and Risk Management, concluded "there is no toxicological basis whatsoever" for the assertion that BD's emissions are "harmful to the public" and "the available data do not support this position." Additionally, based on her assessment, "ethylene oxide concentrations reported in the Covington area are well below any exposure levels that could produce harm." (G. Charnley Aff., attached as Exhibit J, ¶¶ 6, 7.)
- Dr. Michael L Dourson, a board certified toxicologist and former Associate Director of the USEPA Risk Assessment Office, testified the average concentrations from the monitoring points in that submitted by EPD are "well within safety limits" and more than 900 fold below safety levels established by the Occupation Safety and Health Administration (OSHA) for continuous 40-year exposure to workers of 1800 ug/m3, and 4500 fold below the Short Term Exposure Limit of 9000 ug/m3 for protecting the health concerns of workers from 15 minute exposures." Based on his review of the data, Dr. Dourson concluded "I have identified no EtO concentrations, especially considering the overall EtO concentrations detected in the area, that suggest the Covington plant is causing any toxicological concerns." (M. Dourson Aff., attached as Exhibit K, ¶¶ 6, 11.)

B. The Georgia Department of Public Health Has Publicly Stated There Is No Public Health Risk Around the Covington Facility.

EPD and the Georgia Department of Public Health (GDPH) previously admitted there are no known public health risks presented by BD's Covington facility. At the August 19, 2019 ethylene oxide public meeting in Cobb County, at which EPD presented along with USEPA, the GDPH gave a presentation on its analysis of cancer incidence surrounding medical device

sterilization facilities, including BD's Covington facility. (8/19/2019 "Cancer Surveillance in Georgia" Presentation, attached as Exhibit L, at 10, available at https://www.epa.gov/sites/production/files/2019-08/documents/ga_cancer_surveillance_-_cherie_l._drenzek.pdf.) GDPH stated that "[p]reliminary analysis of cancer incidence in the zipcode areas near the facilities did not show increased rates of cancer overall, nor for any of the cancers known to be associated with ethylene oxide." (*Id.*)

C. EPD Admits in the Complaint It Does Not Know What, If Any, Emissions Are Attributable to BD's Covington Facility.

EPD's own allegations in the Complaint demonstrate EPD's lack of evidence of any public health risk. EPD concedes the measured calculations of ethylene oxide "varied wildly." (Compl. ¶ 30.) EPD also admitted their sampling concentrations "included ethylene oxide emitted from other sources." (Compl. ¶ 30.) This is significant as there are many common sources of exposure to ethylene oxide, including other industrial sources in the surrounding area in Covington.

In a report dated October 16, 2019, Montrose Air Quality Services—the same environmental consultant that performed the City of Covington's air sampling—sampled ethylene oxide concentrations from common everyday sources. (10/16/2019 Montrose Report, attached as Exhibit M, at 3.) The results are below:

Table 1: Analytical Results for Everyday Sources. (Worst Case)

Everyday Source	EtO Concentration	
	ppbv	ug/m3
Mercedes Sprinter Bluetec Diesel, idle	100	180
Mercedes Sprinter Bluetec Diesel, revved	140	252
Diesel generator from Sprinter	190	342
Toyota 4 runner, ~2003 model, idle	110	198
Toyota 4 runner, ~2003 model, high RPM	230	414
Gas generator cold start	18,000	32,400
Gas lawn mower cold start	3,000	5,400
Gas lawn mower	450	810
Gas grill	140	252
Charcoal fire	5,000	9,000
Wood fire pit	750	1,350
Kimchi (freshly opened)	1,800	3,240
Kombucha (freshly opened)	400	720
Sauerkraut (freshly opened)	100	180
Kimchi repeat (after sitting)	480	864

(*Id.*) Based on their own admissions, EPD cannot discern at any location what impacts are from BD's Covington facility, other industrial sources, or simple everyday sources like those in the table above.

V. There Is Undisputed Evidence that a Temporary Closure of BD's Covington Facility Will Threaten Public Health and Patient Safety in Georgia.

In its Brief, EPD suggests BD Covington's facility may be "contrary to the public interest." (Br. at 8.) But EPD does not consider the broader ramifications and public health risks created by an immediate shutdown of BD's Covington facility, which is the largest sterilization facility in the State of Georgia. (Johann Fernando Aff., attached as Exhibit H, ¶ 5.)

At its Covington facility, BD sterilizes approximately 15 million medical devices each month. Since October 2018, BD has sold over 101 million urology and critical care medical devices that were sterilized in the Covington facility. (Fernando Aff., ¶ 5.) Of those, over 2.5 million were sold to patients in Georgia and composed more than 1100 different types of medical

devices. (*Id.*) For example, in the last year, the Department of Veterans Affairs alone purchased over 15,000,000 medical devices sterilized at BD's Covington and Madison facilities. (Adam Lotspike Affidavit, attached as Exhibit N, ¶ 3.) During that same timespan, the Department of Defense purchased over 2,200,000 devices with other government agencies purchasing an additional 500,000 devices sterilized at those facilities. (*Id.*)

These devices are used in nearly every hospital and healthcare facility in Georgia, including the Piedmont Healthcare system (and Piedmont Newton Hospital), the Kaiser Permanente system, the Grady Health System, Emory University Hospital, South Georgia Medical Center, WellStar Health System, the Atrium Health system, the AdventHealth system, the Department of Veterans Affairs, Gwinnett Medical Center, St. Mary's Hospital, Lab Corp, Quest, and many others. (Herman Cueto Aff., attached as Exhibit O, ¶ 3; Rian Seger Affidavit, attached as Exhibit P, ¶ 3; Fernando Aff., ¶ 6; Robert A. Johnson Affidavit, attached as Exhibit S, ¶ 3.)

For many of its products, BD has a significant market position, in some cases reaching above 80%. (Cueto Aff., ¶ 5.) For example, BD's Foley catheters are the most widely used across the United States, Canada, and Japan. (Fernando Aff., ¶ 4.) Because of this position, it is unlikely that competitors would have readily available capacity to meet healthcare needs in the event BD's Covington facility was closed and these products were not available. (Cueto Aff., ¶ 6; Seger Aff., ¶ 4; Robert Fredericks Aff., attached as Exhibit Q, ¶ 4; Fernando Aff., ¶ 6.) The impacted devices include urinary and midline catheters, PICC lines, balloon dilation devices, oncology ports, breast biopsy needles, surgical mesh, vascular and ureteral stents, feeding tubes, and drains. (Cueto Aff., ¶ 7; Fredericks Aff., ¶ 3; Fernando Aff., ¶ 4.) In Georgia, there could be more than one hundred thousand patients each month relying on BD devices sterilized in Covington. (Cueto Aff., ¶ 8.)

Recognizing the importance of the Covington facility in the supply of necessary, sterilized medical devices, in July 2019, the FDA expressed concern about the possibility of a shutdown of the Covington facility. Dr. Heather L. Agler, a member of the All-Hazards Readiness, Response, and Cybersecurity team at the FDA stated, "[t]he last thing we want to see is another closure. The capacity for contract sterilizers is already strained. Our biggest concern is any strain actions might cause in terms of medical device availability." [Email from Agler to Shelkey dated 7/30/2019, attached as Exhibit E.]

Just this week, on October 23, 2019, AdvaMed issued a statement regarding this lawsuit and implications of a shutdown of the Covington facility. (10/23/2019 AdvaMed Statement, available at https://www.advamed.org/newsroom/press-releases/advamed-statement-bd-sterilization-plant-georgia.) In the Statement, AdvaMed warned

> With these three facilities closed, procedures for urological conditions, cardiothoracic and lung cancer surgeries, retinal detachments, and tumor ablations are now in jeopardy because, for these devices, there is no other way to sterilize them properly for the patients who need them. Even those entering intensive care units (ICUs) in the coming days could see delays in their care or lack of availability because every patient requires a catheter that must be sterilized with EtO.

(*Id.*)

Additionally, in a letter dated October 21, 2019, various medical societies, including the American College of Cardiology, the American Society of Gastrointestinal Endoscopy, the Heart Rhythm Society, the Society of Interventional Radiology, the Society of Interventional Radiology, the Society of Thoracic Surgeons, and the Society for Cardiovascular Angiography and Interventions, stated the following to the FDA regarding an upcoming Medical Devices Advisory Committee Meeting:

> However, as the Food and Drug Administration has previously acknowledged, many complex medical devices, including but not limited to pacemakers and leads, angioplasty balloons, cardiac catheters, stents, and guiding sheaths, and other

> supplies and equipment used in the care of cardiovascular patients currently rely upon EtO for proper sterilization to ensure patient safety. These complex medical devices currently have limited alternative sterilization processes available while others are suboptimal. Therefore, when considering the overall impact of regulatory changes, the organizations urge the Agency to ensure continued patient access to critical devices as well as to minimize patient costs.

[10/21/2019 Agency Letter to FDA, attached as Exhibit R at 1.]

After EPD filed its Complaint and this Motion, BD contacted other third-party suppliers to determine if there was capacity for sterilization of medical devices that the Covington facility might be prevented from processing. There is no available capacity for sterilization in North America, South America, or Europe.

Additionally, providers who rely on BD devices are concerned over medical device availability and the impact closure of the Covington facility would have on their ability to care for their patients. For example, Dr. Joe Morgan, III, a board-certified vascular surgeon in Albany, Georgia, testified that he purchases many BD devices that are critical for his patient's care and well-bring, including catheters, peripheral arterial balloons, and stents. (J. Morgan, III, M.D., Aff., attached as Exhibit F, ¶ 4.) Dr. Morgan testified that "BD is our key supplier for these products" and "given the limited availability of comparable sterilized medical devices, and given the limited availability of sterilization facilities throughout the United States, the interruption in the supply of BD products, including their catheters, peripheral arterial balloons, and stents, would adversely impact my ability to deliver high-quality medical care to my patients." (*Id.*, ¶ 5.) Dr. Morgan has "not identified any other available supplier of these products that can reliably and reasonably meet our needs." (*Id.*) Dr. Morgan expressed concerns

> At this point, if the BD Bard facility in Covington, Georgia is shut down, I am concerned the lack of supply for these products will immediately impact safety and reliability at our facilities. While a potential shut down will affect our services, we are concerned about the effects of product delays on the lives of the critically ill,

> caregivers, and health care providers and others who rely on these products on a daily basis.

(*Id.*, ¶ 6.)

In sum, the Covington facility is a critical component of the healthcare system in Georgia and the United States. Its closure could have disastrous effects on acute patient care with impacts across Georgia and the United States.

ARGUMENT AND CITATION OF AUTHORITY

In its Complaint and Brief, EPD presents no evidence that warrants shutting down BD's Covington facility. The facility has fully rectified the accidental September release and is complying with all applicable state and federal laws. BD has worked with both EPD and the Georgia Governor's Office and provided all requested information. The harm caused by shuttering the facility, even temporarily, is significant, with potentially disastrous and direct impacts on Georgia patients that rely on medical devices sterilized at the Covington facility. As explained below, EPD is not entitled to an injunction under either O.C.G.A. § 12-9-12 or the traditional four factor balancing test used by Georgia courts.

I. Legal Standard

EPD requests a temporary restraining order under O.C.G.A. § 12-9-12, which states:

> Whenever in the judgment of the director any person has engaged in or is about to engage in any act or practice which constitutes or will constitute an unlawful action under this article, he may take application to the superior court of the county in which the unlawful act or practice has been or is about to be engaged in, or in which jurisdiction is appropriate, for an order enjoining such act or practice or for an order requiring compliance with this article. Upon a showing by the director that such person has engaged in or is about to engage in any such act or practice, a permanent or temporary injunction, restraining order, or other order shall be granted without the necessity of showing lack of an adequate remedy of law.

EPD also claims the traditional factors courts must weigh in determining whether to issue a temporary restraining order support imposition of temporary injunctive relief:

> (1) There is a substantial threat that the moving party will suffer irreparable injury if the injunction is not granted; (2) the threatened injury to the moving party outweighs the threatened harm that the injunction may do to the party being enjoined; (3) there is a substantial likelihood that the moving party will prevail on the merits of her claims at trial; and (4) granting the interlocutory injunction will not disserve the public interest.

Jansen-Nichols v. Colonial Pipeline Co., 295 Ga. 786, 787 (2014).

These four factors are a "balancing test." *City of Waycross v. Pierce Cnty. Bd. of Comm'rs*, 300 Ga. 109, 112 (2016). According to the Supreme Court of Georgia, the "trial court must keep in mind that an interlocutory injunction is an extraordinary remedy, and the power to grant it must be prudently and cautiously exercised." *Id.*

II. EPD Cannot Meet Its Burden for Injunctive Relief under O.C.G.A. § 12-9-12 because BD Has Complied with All Portions of its Permit and the Georgia Air Quality Act.

EPD claims BD violated its Permit and state law in three ways. First, EPD contends the release of ethylene oxide from the Covington facility in September 2019 resulted in a violation of Permit Condition 2.3. Second, EPD alleges fugitive emissions from BD's Covington facility violate Permit Condition 3.1. Third, EPD argues BD violated Ga. Comp. R. & Regs. 391-3-1-.02(2)(a)(1). As discussed below, EPD is incorrect on each count.

A. Permit Condition 2.3 – Ethylene Oxide Destruction Efficiency

EPD alleges BD has violated Permit Condition 2.3, which governs the destruction efficiency of its ethylene oxide emissions from the sterilizer chamber. Permit Condition 2.3 states:

> The ethylene oxide emissions to the atmosphere from each sterilizer chamber vent shall be reduced by at least 99%.
>
> [40 CFR 63 Subpart O; 40 CFR 63.362(c); 40 CFR 70 Avoidance for HAP and VOC.]

(Compl., Ex. A at 2.)

EPD contends that BD violated Permit Condition 2.3 because the release of 54.5 pounds of ethylene oxide dropped the destruction efficiency by less than 2% to 97.3% during the pendency of the leak. (Compl., ¶ 24.) But it is undisputed the release is not ongoing, and all valve outlets have been permanently closed. (R. Pasdon Aff., Ex. C, ¶¶ 7-8.) As a result, it is physically impossible for a similar release to occur in the future. (*Id.*, ¶ 8.) Meanwhile, BD Covington's facility has been achieving more than the required 99% destruction efficiency (99.999%) since the release was stopped. (*Id.*, ¶ 10.) EPD has not explained or justified why an injunction is needed to protect against an accidental release that has been fully resolved and steps have been taken to ensure it cannot happen in the future. Additionally, BD has already agreed to voluntarily install equipment to reduce unregulated fugitive emissions by implementing new controls that will be among the first in the industry to capture fugitive emissions to this extent. (*Id.*, ¶ 14.) BD has already ordered the equipment and is awaiting delivery. (*Id.*)

Even if the accidental release that occurred between September 15 and September 23 could be construed to have been a violation of the Permit, the release is not ongoing and undisputed evidence shows it cannot happen again. EPD has not met its burden to show its need for a

temporary restraining order to enforce Section 2.3 of the Permit. There is nothing for the Court to enjoin.

B. Permit Condition 3.1 and Ga. Comp. R & Regs. 391-3-1-.02(2)(a)(1) – Fugitive Emissions

EPD also claims that BD is violating Permit Condition 3.1 and Ga. Comp. R. & Regs 391-3-1-.02(2)(a)(1), which both address fugitive emissions. Permit Condition 3.1 states:

> The Permittee shall take all reasonable precautions with any operation, process, handling, transportation, or storage facilities to prevent fugitive emissions of air contaminants.

(Compl., Ex. A at 2.) Additionally, Ga. Comp. R & Regs 391-3-1-.02(2)(a)(1) states:

> No person owning, leasing, or controlling the operation of any air contaminant sources shall willfully, negligently or through failure to provide necessary equipment or facilities or to take necessary precautions, cause, permit, or allow the emission from said air contamination source or sources of such quantities of air contaminants as will cause, or tend to cause, by themselves or in conjunction with other air contaminants a condition of air pollution in quantities or characteristics or of a duration which is injurious or which unreasonably interferes with the enjoyment of life or use of property in such area of the State as is affected thereby. Complying with any of the other paragraphs of these rules and regulations or any subparagraphs thereof, shall in no way exempt a person from this provision.

EPD claims that BD has fugitive emissions totaling 555.7 pounds per year (1.52 pounds per day), which EPD claims to be an impermissible amount and a violation of BD's Permit. EPD is incorrect.

Most importantly, there is no regulatory limit for fugitive emissions of ethylene oxide in the Permit. Indeed, there are no state or federal regulatory limits or standards governing the amount of permissible fugitive emissions at all. The term "fugitive emissions" appears nowhere in the Georgia Rules, except with respect to certain defined types of emitting sources that do not apply to the Covington facility. *See, e.g.*, Ga. Comp. R. & Regs. 391-3-1-.02(2)(kk)(2)(vi). And the federal regulations governing ethylene oxide that are incorporated into the Permit require

control of emissions only from the treatment and aeration chambers. *See generally* 40 C.F.R. § 63 Subpart O; 40 C.F.R. § 63.360. BD routinely and effectively controls those emissions as required by the Permit and federal law.

To try and establish a regulatory standard where none otherwise exists, EPD refers to calculations contained in Appendix A of EPD's Guideline for Ambient Impact Assessment of Toxic Air Pollutant Emissions. (Comp., ¶ 14.) But none of the calculations in that document represent a promulgated ambient air standard or a fugitive emission standard. Rather, these alleged "limits" are simply guidelines to be used during the permit application process and may suggest the need for a permit applicant (not a permittee) to conduct some additional investigation. For example, the referenced document says

> The guidelines will be used in the review of air quality permit applications to construct/modify potential sources which emit any Toxic Air Pollutant (TAP) listed in Appendix A of this guideline document with emissions above the Minimum Emission Rate (MER) and in other cases at the Director's discretion.

(Georgia Air Toxics Screening Guidelines at 1.)

BD is a fully-permitted and operating facility. The guidelines cited by EPD are irrelevant and impose no obligation or regulatory standard limiting fugitive emissions at the Covington facility. If EPD wanted to apply these guidelines to BD as a regulatory limit, the Georgia Administrative Procedure Act, O.C.G.A. § 50-13-1, *et seq.*, requires that EPD allow BD and all other Georgia citizens an opportunity to exercise their rights to comment and participate under the law. Furthermore, BD has data to demonstrate that air samples from the exhaust of the warehouse (primary source of fugitive emissions) are less than 1ppm, and that BD is therefore meeting the federal emissions standards.

In short, the calculation upon which EPD tries to rely and in turn to try and establish a violation of Permit Condition 3.1 and Ga. Comp. R. & Regs 391-3-1-.02(2)(a)(1) is not a

regulation. It is not a limit. And it is referenced nowhere in the Permit. It cannot serve as the basis for finding that BD's fugitive emissions at the Covington facility violate the Permit.

Finally, EPD also claims that "BD has demonstrated an unwillingness to take the steps necessary to accomplish the [unregulated fugitive emission] reductions in a timely manner." Again, EPD has no evidence to support this statement. To the contrary, the evidence demonstrates that BD already employs reasonable measures and practices to control its unregulated fugitive emissions from its operations, processes, handling, transportation, and storage of ethylene oxide at the Covington Facility. (Pasdon Aff., Ex. C, ¶ 14.). BD has done this despite EPD's instruction that BD did not need to take any additional measures until USEPA finalized emissions standards under the NESHAP for Commercial Sterilizers, which may be issued by the end of 2019.[1] (E. Kondracki Aff., attached as Exhibit A-1, ¶ 4.)

III. EPD Has Not and Cannot Satisfy the Factors Necessary for a Preliminary Injunction.

Each of the four factors that courts traditionally consider when determining whether to impose a preliminary injunction weigh in favor of BD and only underscore why a temporary shutdown is inappropriate.

A. BD, Not EPD, Will Suffer Irreparable Injury if the TRO is Granted.

According to the Supreme Court of Georgia, "[t]he first factor—substantial threat of irreparable injury if an interlocutory injunction is not entered—is the most important one, given that the main purpose of an interlocutory injunction is to preserve the status quo temporarily to

[1] In a Federal Register notice, U.S. EPA recently notified the public of the agency's intention to collect information to allow additional control of ethylene oxide for the "National Emission Standards for Hazardous Air Pollutants (NESHAP) for Commercial Ethylene Oxide Sterilization and Fumigation Operations apply to both new and existing commercial ethylene oxide (E.O.) sterilization and fumigation facilities using one ton of E.O. (as defined in 40 CFR 63.361) after December 6, 1994." Docket No. EPA-HQ-OECA-2012-0664. (84 FR 50825, Sept. 26, 2019).

allow the parties and the court time to try the case in an orderly manner." *City of Waycross*, 300 Ga. at 111. When courts consider the need to preserve the status quo, the focus is on whether court action is necessary to protect the applicant's interest until a final determination on the merits. *See Price v. Empire Land Co.*, 218 Ga. 80, 85-86 (1962) (the evidence in that case "did not disclose that an injunction would be necessary to protect the plaintiff's interests during the pendency of the suit"). Injunctions are not appropriate "to allay mere apprehensions of injury, but only where the injury is imminent and irreparable." *Lue v. Eady*, 297 Ga. 321, 329 (2015).

EPD does not even address this first, "most important," element. Nor does EPD articulate how it or the public is at risk of irreparable injury during the pendency of the lawsuit. Indeed, EPD is silent on what the supposed "irreparable injury" would be. While EPD suggests there may be an increased risk of cancer incidence from continuous inhalation exposure to ethylene oxide over an entire lifetime, they do not attempt to quantify how that risk is congruent or translates to the relatively low and limited exposure that occurred during the accidental eight-day release in September. EPD fails to explain how a possible future risk, measured by continuous exposure over decades, requires the immediate closure of the Covington facility, especially when the cause of the accidental release has been permanently corrected and emission numbers have returned to normal.

EPD provides no evidence, toxicological assessment, engineering calculations, public health modeling, or anything else that shows there is any risk to anyone from ongoing medical device sterilization at BD's Covington facility. To the contrary, the undisputed evidence shows that on August 5, 2019, GPDH informed the City of Covington residents that BD's Covington facility posed no public health risk. (8/19/2019 GDPH Presentation, Ex. L.) Given this lack of

"imminent irreparable injury," there is no "vital necessity" for the injunction. *Hipster, Inc. v. Augusta Mall P'ship*, 291 Ga. App. 273, 275 (2008).

B. The Harm to BD Outweighs Any Risk to EPD.

The second factor "requires a balancing of the relative equities of the parties." *W. Sky Fin., LLC v. State ex rel. Olens*, 300 Ga. 340, 354 (2016). Under this factor, "an interlocutory injunction should be refused where its grant would operate oppressively on the defendant's rights, especially in such a case that the denial of the temporary injunction would not work irreparable injury to the plaintiff or leave the plaintiff practically remediless in the event it should thereafter establish the truth of its contention." *Garden Hills Civic Ass'n, Inc. v. Metropolitan Atlanta Rapid Transit Authority*, 273 Ga. 280, 281-82 (2000) (quoting *McKinnon v. Neugent*, 226 Ga. 331, 332 (1970) (internal quotation marks omitted).

It is undisputed that BD's Covington facility is fully-permitted. It is undisputed that BD is currently in full compliance with its Permit and all applicable state and federal laws. It is undisputed that BD quickly corrected the cause of the September accidental release and implemented a permanent solution that makes it impossible for similar leaks to occur in the future. Additionally, it is undisputed that BD has already agreed to make voluntary changes at the Covington facility and purchased the necessary equipment to reduce its unregulated fugitive emissions to an extent that is not currently in place anywhere else across the industry. (Pasdon Aff., Ex. C, ¶ 14.) Currently, BD is operating the Covington facility above industry standards for medical device sterilization facilities throughout the United States.

Given these realities, EPD's use of the threat of a closure of the facility is the equivalent of a regulatory sledgehammer that would harm BD's right to continue operating consistent with its state-issued permit and in turn to provide critically necessary medical devices to vulnerable

Georgians. To the extent EPD seeks modifications to BD's Permit, BD has already agreed to submit those changes by October 31, 2019, and they will be subject to administratively required procedures under Georgia's Administrative Practice Act. Balancing the relevant equities weighs against issuance of a temporary restraining order.

C. EPD Will Not Prevail on the Merits of Its Claim at Trial.

Under the third factor requiring a showing of an applicant's substantial likelihood of success on the merits, "if the trial court determines that the law and facts are so adverse to a plaintiff's position that a final order in his favor is unlikely, it may be justified in denying the temporary injunction because of the inconvenience and harm to the defendant if the injunction were granted." *Kennedy v. Shave Barber Co., LLC*, 348 Ga. App. 298, 306 (2018).

As discussed in Section II above, EPD cannot prevail on the merits of its claims at trial. It is undisputed there is no ongoing violation of Permit Condition 2.3, and corrective actions have already been taken to ensure a similar leak cannot occur in the future. It is also undisputed EPD cannot prove a violation of Permit Condition 3.1 as there are no promulgated regulatory limits governing ethylene oxide fugitive emissions and BD already has in place reasonable measures to limit such emissions. To underscore this point, BD has already implemented the three actions EPD requested in its Complaint: (1) training of staff at the Covington facility; (2) corrective action to permanently close all vacuum exhaust valves; and (3) ordered additional equipment to further limit its ethylene oxide fugitive emissions. (Compl. at 15-16.) The injunction is moot.

D. Granting the TRO Will Harm the Public Interest.

To fulfill the fourth factor, the applicant must provide "evidence supporting . . . [a] determination that the public interest, i.e. the public as a whole, will not be disserved by the grant

of the interlocutory injunction." *City of Waycross v. Pierce Cty. Bd. Comm'rs*, 300 Ga. 109, 113 (2016).

In its Brief, EPD claims, again without proof, that the September 2019 release of 54.5 pounds of ethylene oxide and BD's fugitive emissions is "harmful to the public." (Br. at 8.) The undisputed record, however, which consists of sworn testimony from three board-certified toxicologists and physicians, demonstrates unequivocally there is no evidence of any public health risk whatsoever. (*Supra* Fact Section IV.A.) Dr. Borak testified that the "available data do not support" EPD's suggestion that BD's ethylene oxide emissions were "harmful to the public." (Borak Aff., Ex. I, ¶ 10.) Likewise, Dr. Charnley concluded "there is no toxicological basis whatsoever" for the assertion that BD's emissions are harmful to the public. (Charnley Aff., Ex. J, ¶¶ 6-7.) EPD has failed to satisfy its evidentiary burden.

But EPD also ignores a very real and imminent public health risk if the Covington facility is shut down. The Covington facility is a critical component of the sterilized medical device supply chain in Georgia and across the United States. At the Covington facility alone, more than 15 million medical devices are sterilized each month. (*Supra* Fact Section V; H. Cueto Aff., Ex. O, ¶ 3-5.) These devices are used at nearly every hospital, healthcare facility, and physician office in Georgia, including those in Covington. (*Id.*, ¶ 4.)

Dr. Joe Morgan, a board-certified vascular surgeon in Albany, Georgia, testified that BD's devices are critical to his practice and any interruption in his supply of these products "would adversely impact my ability to deliver high-quality medical care to my patients." (Morgan Aff., Ex. F, ¶ 5.) Because he has been unable to identify any other available supplier of these products that can "reliably and reasonably meet our needs," he is concerned that if the Covington facility is

shutdown, "the lack of supply for these products will immediately impact safety and reliability at our facilities." (*Id.*, ¶ 6.)

Dr. Morgan is not alone in his concern. The FDA, the federal agency that regulates the medical device industry, fears the impact of the closure of another sterilization facility:

> The last thing we want to see is another closure. The capacity for contract sterilizers is already strained. Our biggest concern is any strain actions might cause in terms of medical device availability.

(Ex. F.) Other industry groups echo the FDA on this point. Just this week, and in response to this lawsuit and EPD's Motion, AdvaMed warned that if the Covington facility was closed, even temporarily, "procedures for urological conditions, cardiothoracic and lung cancer surgeries, retinal detachments, and tumor ablations" would be in jeopardy. (Ex. F.) "Even those entering intensive care units (ICUs) in the coming days could see delays in their care or lack of availability because every patient requires a catheter that must be sterilized with EtO." (*Id.*)

This evidence is undisputed and overwhelming. Closure of the Covington facility would immediately and directly put Georgia patients at risk of not receiving the lifesaving medical devices they need. The Court must weigh the unsupported, unsubstantiated and generalized claims that the Covington facility is not in the "public's interest" against the testimony and undisputed evidence from surgeons from southwest Georgia to the FDA in Washington, D.C. that shuttering the Covington facility poses a very real and imminent public health crisis.

CONCLUSION

BD welcomes the opportunity to resolve this issue with EPD. But BD does not believe injunctive relief is appropriate to shutdown the Covington facility when it is complying with its Permit and all applicable state and federal laws and when shutdown would have a significant impact on the already strained supply of critical sterilized medical devices.

Respectfully submitted this 25th day of October, 2019.

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