COMPANY STATEMENT

Aug. 22, 2019

The Atlanta Journal-Constitution Weekend Story on Ethylene Oxide

The Atlanta Journal-Constitution (AJC) is planning a weekend story about medical sterilization facilities in the greater Atlanta area and their use of ethylene oxide to sterilize medical devices to protect patients from the risks of infectious diseases caused by bacteria, viruses and fungi, all of which is essential to a functioning and effective health care system. AJC submitted a number of questions to BD as part of its reporting for the story. Because we recognize that space limitations would make it impossible for the AJC to share all information we provided in its entirety, BD is publicly sharing the questions from the AJC and answers provided to them by BD. As part of our commitment to full transparency, BD wants to ensure the greater Atlanta area and our communities in Covington and Madison have the full context of the information provided to the AJC.

Q: How long has the plant been in operation, and in what year did it begin using ethylene oxide (EtO)?

A: BD is a global medical technology manufacturer, and both BD and Bard have a 100+ year history of being leaders in medical device innovation. The company has a long history of medical industry "firsts" including developing the first insulin syringe (1924), the first Foley urinary catheter (1934), the first blood collection tubes (1949), the first single-use IV catheter (1957), the first latex balloon catheter, the first smart infusion pump (1988), the first FDA-approved drug coated balloon and many more. BD products are ubiquitous throughout hospitals, labs and doctor's offices and are critical to the global health care industry.

BD has been a member of the Covington community since 1967, when C. R. Bard, Inc. opened the facility. BD completed the acquisition of Bard in December 2017. Our operations in Covington include the headquarters of BD's Urology and Critical Care business, our sterilization facility, which also includes procedure kitting operations and a global distribution center. BD employs approximately 830 full-time employees and 180 temporary employees in Covington and about 50 full time employees in Madison.

Our current ethylene oxide (EtO) sterilization facility has been operating since 1991 and has been continually maintained and upgraded to employ the best available emission technology. For example, when the current facility opened, we employed acid scrubbers as our primary emission reduction technology. When thermal oxidizers came into existence in the late 1990's, we evaluated the technology and determined they would provide more efficient destruction of ethylene oxide and made the investment to upgrade to thermal oxidation technology, which enables more than 99.95% destruction of ethylene oxide. Unlike acid scrubbers that convert ethylene oxide to ethylene glycol (a hazardous waste that requires proper disposal), thermal oxidation incinerates ethylene oxide at 1,500 degrees Fahrenheit and breaks it down into carbon dioxide and water, leaving no hazardous waste.

Prior to 1991, Bard conducted sterilization, but it was based on a process using mostly Freon-12 and about 12% ethylene oxide. When regulations around Freon and other chlorofluorocarbons were enacted to protect against ozone deterioration, the medical product industry moved to a process

using 100% ethylene oxide. The plant built in 1991 was designed specifically for 100% ethylene oxide sterilization.

Throughout BD's 120-year history, providing sterile medical devices has been central to the products we provide and the patients we serve. The company is primarily a manufacturer, but we also sterilize the products we manufacture as part of the overall process. We helped to pioneer the safe use of sterilization techniques, including EtO, through investment and development of subject matter experts in the science of sterility assurance and process safety engineering for sterilization facilities.

The ethylene oxide used in industry to sterilize medical devices is less than 1% of ethylene oxide produced. The majority is used as an intermediary to produce many products, such as certain plastics, household cleaners, safety glass, adhesives, textiles and detergents. Ethylene oxide also is a naturally occurring substance created in nature, including by the human body.

A follow up question about EO sterilization in Covington. The answer from the company said it opened its current EO facility in 1991. Did it sterilize anything using EO before 1991? If so, when did the company start using EO for sterilization in Covington?

A: In our original response, we stated that prior to 1991, Bard conducted sterilization, but it was based on a process using mostly Freon-12 and about 12% ethylene oxide. When regulations around Freon and other chlorofluorocarbons were enacted to protect against ozone deterioration, the medical product industry moved to a process using 100% ethylene oxide. The Freon-12 and 12% ethylene oxide sterilization operation began when the site opened in 1967. In 1991, the new facility was built, and we have been using the 100% ethylene oxide process since then.

Q: What products are manufactured/sterilized there?

A: The vast majority of products sterilized in Georgia are considered "interventional" products, which means they are used in procedures and come in direct contact with the human body. Major categories of products include urinary catheters, ports, dialysis catheters, hernia mesh, balloon devices that help open obstructed blood vessels, and stents and grafts used for peripheral arterial disease. Products like urinary catheters are used in surgical procedures where anesthesia is used, so it isn't only products that help treat specific diseases and conditions like hernias and peripheral arterial disease, but "enabling" products for a wide range of procedures and surgeries. Many of these products are designated as "critical to care," which means they are essential to a functioning and effective health care system. Some examples include:

- 500,000+ ports are placed annually in the United States. The majority are related to cancer treatment. Nearly 8 out of 10 ports placed in the United States are BD ports.
- 450,000+ patients are on dialysis in the United States. Approximately 80% of these patients start on dialysis catheters. BD is the #1 dialysis catheter manufacturer in the U.S.
- Over 600,000+ dialysis access procedures/interventions are done annually to maintain or restore dialysis. BD is the #1 manufacturer of these treatment solutions which include angioplasty balloons, covered stents, etc.

Q: How much product is sterilized there per week, month or year?

A: Globally, BD manufactures billions of products each year. At our sites in Covington and Madison, we sterilize about 240 million BD medical devices annually. These medical devices are critical to our health care system and serve patients across the U.S. and around the world, and ethylene oxide sterilization is used to protect patients from the risks of infectious diseases caused by bacteria,

viruses and fungi. EtO sterilization is used for these types of medical devices because there currently is no other way to make them safe for patient use. Our employees in Covington and Madison take great pride in what they do and the positive impact they have on the millions of patients worldwide.

Q: Are any other sterilization methods used there, and if so, what are they?

A: No. The other predominant modes of sterilization include steam/heat-based sterilization and radiation-based sterilization including electron beam and gamma radiation. However, these types of sterilization can damage some types of medical products because of material sensitivities and/or the complexity of design. Also, electron beam and gamma radiation capacity is limited to minimize the proliferation of radiation. That leaves ethylene oxide as the only mode of sterilization for many medical products.

However, the FDA and the medical technology industry have been working on alternatives. On July 15, the FDA launched an innovation challenge to identify new sterilization methods and technologies as an alternative to EtO and reduce EtO emissions. BD will be actively participating in this challenge in collaboration with other industry organizations, and we plan to participate in an FDA advisory committee meeting on this topic in November.

Q: How many chambers are in operation using EtO?

A: In Covington we have 5 chambers and in Madison we have 7 chambers. Our sterilization process is fully automated, unlike many other sterilizers. The sterilization process consists of three phases: Pre-conditioning, sterilization and aeration. Our process is fully automated and under vacuum when moving from one phase to the other, using carts that are remotely controlled outside of the chambers. Without full automation, workers are required to use forklifts and enter the chambers, which can create a higher risk of ethylene oxide exposure to the workforce. The full process takes about 36 hours to complete. That includes 8 hours of preconditioning when the product is heated to 130 degrees Fahrenheit, 8 hours of ethylene oxide exposure and 16 hours of aeration to remove ethylene oxide emissions to trace levels as required by EPA and OSHA regulations and FDA standards.

Q: Do any of the chambers have scrubbers or other emissions controls on their backvents?

A: Yes. All chambers in both Covington and Madison capture and control backvent exhaust. All emissions from the entire sterilization process are controlled under vacuum pressure and routed to a regenerative thermal oxidizer for incineration to 99.95% destruction efficiency, which is significantly higher than the 99% requirement. This includes all backvent exhaust from all chambers.

Q: If so, for how long have these backvents had scrubber or other controls?

A: We have been routing backvent exhaust to the thermal oxidizer, since it was installed in 1997. We continued to capture backvent exhaust, even after U.S. EPA rescinded this requirement, because it provides a safer sterilization approach for both employees and our communities. This is one example of how BD has taken a leadership approach to continuous improvement in EtO sterilization, long before any public scrutiny or political pressure. As your research has probably shown, some companies do not currently capture and treat backvent exhaust and some have only recently done so. BD has been doing this since 1997 in Covington. When the Madison facility was built in 2006,

we included all of the same safety and environmental controls at that facility, including a regenerative thermal oxidizer, backvent exhaust that routes to the oxidizer, and a fully automated sterilization process.

Follow Up Question: The plant has been using a 100% ethylene oxide process since 1991? All 5 chambers have had scrubbers (backvent exhaust routed to a thermal oxidizer) since 1997?

A: You are correct that BD has been using 100% ethylene oxide process since 1991, however your terminology in the second sentence is not correct. For background, there are two primary ways to control ethylene oxide stack emissions: Acid scrubbers and thermal oxidizers. Since 1997, BD has used a thermal oxidizer as our primary means of destroying ethylene oxide emissions. So it is incorrect to say that BD uses scrubbers. We use a thermal oxidizer, which is the best available technology. As I stated in the original list of answers, unlike acid scrubbers that convert ethylene oxide to ethylene glycol (a hazardous waste that requires proper disposal), thermal oxidation incinerates ethylene oxide at 1,500 degrees Fahrenheit and breaks it down into carbon dioxide and water, leaving no hazardous waste. But it is correct to say that BD has been capturing backvent exhaust and routed to a thermal oxidizer since 1997 and the backvent exhaust is destroyed at the same 99.95% destruction efficiency as all other exhaust throughout the sterilization process. We had four chambers in 1997. We added a 5th chamber in 2012, and we have captured all backvent exhaust since 1997.

Q: If not, are new backvent controls part of BD's planned emissions improvements as described Tuesday?

A: See above. Already been capturing backvent exhaust for 20+ years.

Q: What other emission controls, if any, are part of BD's planned $8 million investment?

A: BD committed to design and install new emission reduction technologies and processes to further reduce fugitive emissions. This includes capturing all exhaust from the warehouse and run it through a reactive dry bed system that would absorb residual trace emissions of ethylene oxide. The application of this dry bed system to capture fugitive emissions is something the industry is doing to innovate new ways of capturing very low concentration levels of EtO – sometimes already below what can be detected in ambient air monitoring. The company also presented a plan to have an independent company validate its current stack emissions destruction of 99.95%, which is significantly better than the 99% regulatory requirement.

Q: The company's website says it is "going beyond government requirements for ethylene oxide (EtO) emissions to ensure safe operations for employees and the local community… We continue to take all steps necessary to ensure the safe operation of our facilities, and we are confident our emissions are below all government requirements." At what level of emissions is the company operating for EtO, and how does that compare to the government requirement?

A: Based on the amount of ethylene oxide BD used in 2018, our air permit would have allowed for more than 10,000 pounds of ethylene oxide emissions. However, because of the voluntary technology investments and continuous process improvements made at our facility in Covington, our facility generated 656.3 pounds in 2018 versus the approximate 10,000 pound limit in our permit. That means that today, before any updates to the facility are made, we currently emit 95% fewer emissions than what is required by law.

The recent ambient air test in DeKalb County recorded EtO levels of 0.3 micrograms per cubic meter, which is consistent with many other metropolitan areas. This is because EtO is a very common chemical used to produce many products, such as certain plastics, household cleaners, safety glass, adhesives, textiles and detergents. EtO emissions are also produced by plant decay, vehicle exhaust, cooking oils, cigarette smoke and other sources, including the human body. For context, the highest level of EtO modeled by Georgia EPD in any residential neighborhood surrounding the BD facilities is 0.03 micrograms per cubic meter, an amount 10 times lower than the results of Georgia EPD's recent ambient air test.

We are confident in our controls and that our emissions are not putting any of our communities at risk. If there are higher incidences of cancer, a total view of what is happening in the environment must be looked at, not just a singular industrial source. In fact, the Department of Public Health stated in the original WebMD story that "its data shouldn't be seen as a link between any particular environmental exposure and a specific type of cancer. That's particularly true in some of the impacted neighborhoods in Covington, which have had documented exposures to other types of toxic chemicals in addition to ethylene oxide." Ethylene oxide exists almost everywhere, in the air and even in the human body. Our bodies produce EtO as a normal product of metabolism. EtO is present in many everyday products from food to autos to clothing and even shampoo. And while the 2018 National Air Toxics Assessment (NATA) from US EPA did show elevated cancer risk in certain areas around Atlanta, because EtO is so omnipresent in the atmosphere it is literally impossible for air monitoring to ascribe this elevation to a singular source of EtO due to the variables of wind, temperature and other conditions.

Follow Up Question: According to the EPA's Toxics Release Inventory, the Covington plant emitted 5,605 pounds in 2017 and 6,294 pounds in 2016.

A: As part of the modeling exercise for Georgia EPD, we reviewed our historic emission data in December 2018 and determined Bard's historical methodology to calculate emissions was based on our permit requirement (99% destruction efficiency) rather than the industry practice of using the actual DRE, which in this case, testing performed by a third party had determined to be greater than 99.95%. In December 2018, working with the Georgia EPD, we agreed to update our emission data by using the actual DRE and provide this more accurate data to the Georgia EPD for modeling purposes. We are providing emissions data on this basis to both the EPA and the Georgia EPD going forward, including the data filed by the Covington site for the 2018 TRI filing that was submitted on July 1, 2019. This brings reporting from Covington in line with industry practice and BD standards for emissions reporting. If you go beyond 2014, you will see numbers based on the historical methodology that are much higher than what the actual emissions were. We did not go back to update years prior to 2014, because they were outside of EPD's five-year modeling window.

Reported emissions from the past five years are below:

Year	Covington EtO Emissions
2018	656.3 pounds
2017	657.4 pounds
2016	726.9 pounds
2015	771.2 pounds
2014	692.6 pounds

You will find these updated on EPA's website at: https://enviro.epa.gov/facts/tri/ef-facilities/#/Release/30209CRBRD8195N