

# COMPANY STATEMENT



**Oct. 21, 2019**

BD is a safely operating company that is in full compliance with its permits, has proactively adopted the most advanced and best available technology and is emitting a fraction of its allowable limit. The Attorney General's action is an unnecessary move given the company's high level of cooperation and is inconsistent with our continued dialogue with the state to implement voluntary improvements at our Covington facility. We are concerned about the risk the State of Georgia's actions poses to the patients our products serve in Georgia and nationwide.

We will vigorously defend the company and patients' ability to access critical medical devices using science-based evidence to ensure that patients are not harmed from unnecessary decisions by the State of Georgia that are not based on sound legal or scientific grounds.

We have been in discussions with the Georgia Environmental Protection Division (EPD) since August on our voluntary investment of \$8 million of improvements. Governor Brian Kemp, the Georgia EPD and Mayor Johnston are ignoring science and facts and may be creating a risk to the health and safety of patients, including the elderly and children that rely on these devices to deliver critical interventions. The company and the technology we have used in Covington represents the best available and was recently validated by a third-party testing firm to have a 99.999% destruction efficiency.

As BD stated in a letter to Governor Kemp last week, the EPD has aided consistent misunderstanding and misplaced public hysteria about ethylene oxide. This letter was the latest in BD's many attempts over the past several months to work productively with the Governor, EPD and local officials to engage in open, productive and transparent discussions around our shared commitment to public and employee safety.

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October 17, 2019

The Honorable Brian Kemp  
Governor  
206 Washington Street  
Suite 203, State Capitol  
Atlanta, GA 30334

Dear Governor Kemp,

BD appreciated the opportunity to meet with you and the leadership of the Georgia Environmental Protection Division (EPD) in August to discuss our shared commitment to public safety. However, we are profoundly disappointed by the escalating disruptive business environment in Georgia which is a result of decisions made by the EPD. The actions that EPD has taken subsequent to our meeting do not align with the expectations that you conveyed to all parties.

This new norm is born from an incomplete understanding of employee and community protections at our facilities in Covington and Madison, the science of emissions destruction, as well as the purpose and limitations of risk modeling for screening versus actual threat to human health and the environment. The media's consistent misunderstanding certainly has exacerbated this situation. The current public discourse leaves us concerned about the lack of a rational and fact based discussion on this important topic. When we met in August, we committed to work collaboratively to improve our processes that are designed to sterilize lifesaving medical devices. However, our partnership with EPD has gotten off track, and we need your leadership to return to the shared goals that we discussed during that meeting.

BD is in full compliance with all laws, operates well within regulatory limits, is proactively transparent and has made a commitment to continue to lead technologically in emissions minimization and sterilization processes. We thought that we were working productively with the EPD, including weekly conversations on permitting for improvements that we are not required to complete, as well as the stack emissions testing which was proven to destroy EtO at 99.999% efficiency, even better than previously known. However, the statement below by EPD only serves to alarm the citizens of Covington by advancing false statements regarding our voluntary report of a release of EtO at our facility. In addition, the statement points to limited air sampling results as "deeply troubling" to which every toxicologist with whom we work believes is alarmist and inaccurate.

**Advancing the world of health**

As a courtesy, EPD's written statement is provided below:

*Over the course of eight days starting on September 15, 2019, the Covington BD facility experienced a malfunction, resulting in the release of roughly 54.5 pounds of ethylene oxide. Inexplicably, the facility failed to properly notify the Georgia Environmental Protection Division (EPD). During this time, local officials were testing ambient air in areas surrounding the facility for the presence of ethylene oxide. EPD began its own air testing on October 3, 2019. Although the state's data is not yet finalized, EPD plans to publish it online as early as next week. EPD is uncertain of the impact that the facility's ethylene oxide leak may have had on Covington's results.*

*Due to this leak, EPD has opened an investigation into the Covington BD facility. The safety of Georgia families remains the state's top priority, and BD will be held accountable to the fullest extent available under current law. State officials cannot comment on the specifics of the investigation at this time.*

*The City of Covington's air testing results are deeply troubling. Based on these results, EPD will deploy more equipment to double testing frequency and determine what regulatory action may be necessary for the surrounding community's safety.*

*The Governor and EPD are working together to name an environmental task force of stakeholders and subject-matter experts for recommendations on the regulation of medical sterilization companies and ethylene oxide use in Georgia.*

This type of inaccurate and misleading statement only serves to fuel distrust by the communities we serve. In addition, we have endeavored to use science and experts to ensure that we are acting in the most responsible way. Our consulting toxicologists, while remunerated by us, are to themselves and the science true, which is in keeping with our way of doing business. They are at a loss to understand who is formulating EPD's concern, their scientific expertise and why they are not collaborating with same type of experts that BD has engaged. The conversation should be about real and science based risks and data so that we can adequately address the concerns of the community and continue a collaborative dialogue. It is critical that the public understand the amount of EtO emitted from everyday sources, which have EtO emission levels that far surpass any levels measured anywhere around Covington.

As mentioned above and with regard to the recent unintended release of EtO, attached you will find our detailed response to EPD's statement, including a history of our interaction with EPD relating to our voluntary notification to the EPD, the City of Covington and your office. You will see quite clearly that while the unintended release did not meet the reporting requirement threshold, we nonetheless reported it consistent with our commitment to transparency. In addition, we notified EPD of the unintended release well in advance of the testing that they initiated on October 3 referenced in the EPD statement above.

Our company's primary core value is doing what is right, and we take our 125 year reputation of integrity very seriously. Any direct or indirect utterance that BD in any way acted improperly is completely false.

BD reiterates our continued commitment to transparency and our focus on running the very best operation we possibly can. Over the last two months, we have invited in and hosted a dozen elected officials and several media outlets. EPD leadership and your staff has and will continue have an open invitation in the spirit of transparency and public private partnership.

Our company has been an integral part of the Covington community for decades, providing essential jobs and investment, as we work to bring critical medical devices to market in order to deliver healthcare to patients in Georgia and beyond. We are confident in the safety of our plant, the skill and competence of our employees and the effectiveness of our processes. We also know that until science has a seat at the table, the hysteria over EtO will not be adequately addressed. We believe that the organization of an environmental task force is a step in the right direction, but only if it includes participation by certified toxicologists, air pollution control experts and independent regulatory experts.

In addition to ensuring the safety of the public and the communities, there is another unintended consequence of ignoring the science of sterilization and that is the potential disruption to the supply chain and the devastating impact to patients in Georgia and elsewhere in the US if medical devices do not get sterilized and delivered to healthcare providers. Over 250 million of the 20 billion medical devices sterilized a year are sterilized at our facilities in Covington/Madison. There is not enough capacity in the North American sterilization network industry-wide to make up for the loss of BD facilities in Georgia. This is not something that can be simply ignored as if it does not affect Georgians, because it certainly would.

Thank you for the opportunity to share with you our greatest concerns. We remain committed to work collaboratively and transparently, and we look forward to your continued leadership on this important topic.

Very truly yours,



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