Food and Drug Administration: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting Announcement
Docket No. FDA-2019-N-3793
November 6, 2019

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Thank you to the FDA and advisory committee members for the opportunity to provide comments today. My name is Chaun Powell and I serve as the Group Vice President of Strategic Supplier Engagement for Premier.

Premier is a leading healthcare improvement company, uniting 4,000 U.S. hospitals and health systems and approximately 175,000 other providers and organizations to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost.

In my role, I am personally responsible for the contractual relationship that our health systems maintain with over 1300 suppliers and work side-by-side with healthcare providers to manage, forecast and deliver the medical devices they need to offer high-quality care to patients. At Premier, our goal is to ensure that providers have access to the right products at the right time for their patients, and this is why we have been working proactively to ensure that recent sterilization facility closures do not result in supply chain disruptions or impact patient care.

Premier is equally dedicated to weighing environmental responsibilities with our ability to sustain patient care across the country. ***Premier is committed to working with the FDA, EPA, and stakeholders to find a sustainable approach and path forward that addresses the concerns with ethylene oxide while carefully considering the unintended negative consequences that sterilization facility closures would have on patient care.***

Premier has proactively taken three steps to identify and mitigate the potential impact of the sterilization plant closures to date, as well as those that are at risk of closure.

First, Premier created a product disruptions team to track, mitigate and respond to device disruptions.

Whereas regulations for drugs are prescriptive and mandate that drug manufacturers alert the FDA when supply chain interruptions or shortages occur, similar regulations do not exist for devices. Premier has stepped in to fill this void and has dedicated team members to trace and monitor the inventory of products that flow through these sterilization sites. We created a healthcare product disruptions team to collaborate with suppliers; collect real-time information on the flow of inventory through sterilization

facilities; and analyze which products' availability may be impacted and for how long. The result is that we now have a program in place for disruption activation, response, and recovery, which will make our members stronger and more efficient as other sterilization sites face potential closure. The success of this process, however, is predicated on the availability of sterilization capacity, which remains in jeopardy.

Second, Premier quantified the current state of EtO sterilization and the potential downstream impact to product disruptions.

As the threat of additional closures became more public, we knew that we had to assess the potential downstream risk. To do this, we proactively surveyed over 600 suppliers to determine:

- In what states they sterilize products;
- The form of sterilization used;
- Alternative sterilization methods that are validated for their products; and
- Redundancy and contingency plans for sterilization without EtO.

Our survey identified EtO sterilization in 21 unique locations across 13 states and 7 countries. As many of my counterparts have shared, suppliers noted that there are no viable alternatives for sterilization of these products without significant research and development and supplemental applications to the FDA.

The most alarming trend, however, was that only 3 percent of respondents declared that there was legitimate risk of product disruption to their supply chain due to their redundancy and contingency plans. This statistic was reassuring at first, until we realized that it was grounded in conjecture. Suppliers assumed that excess EtO sterilization capacity existed and that sterilization of their products could simply be transferred to that excess capacity. Perhaps prior to the first sterilization facility closure, those alternate facilities had capacity to take on new suppliers. However, as additional closures occurred, Premier questioned the level of excess capacity that remained available. This brings me to my third and final point.

Third, Premier quantified the availability of excess sterilization capacity in the US and determined that capacity is nearly exhausted.

Based on primary research, we identified that most third-party EtO sterilization facilities are operating currently at 90 percent capacity. Using that statistic and two different calculations that identified that the average facility sterilizes 200 million units per year, we established that the excess sterilization capacity in the U.S. was approximately 1 billion units prior to any closures. Following the closure of Sterigenics in Illinois, Viant in Michigan, and Sterigenics in Georgia, the current excess capacity is 520 million units.

The estimated capacity at Medline in Illinois and BD in Georgia is 550 million units. Simple math shows that if those two plants close, or any similarly sized plants close, we will exceed the excess sterilization capacity for current FDA-approved facilities in the U.S.

Two more sterilization facility closures is our threshold and would not only send our healthcare supply chain into a tailspin, it would be catastrophic for patient care.

So where do we go from here? Premier proposes two near-term solutions.

First, we must create visibility to upstream stakeholders in the supply chain. This includes raw material suppliers as well as packagers and sterilization locations. This visibility will help us prevent, estimate the impact of, and mitigate disruptions of all kinds. Absent true visibility into our suppliers, packagers and sterilization locations, we cannot predict and proactively address any disruptions.

Second, we must lever the solutions that have been successful to address drug shortages and apply them to medical devices. The FDA should have similar authority to address shortages for medical devices as they do with drugs. We must also work together between the public and private sector to find more effective means of disruption prediction, prevention and mitigation.

In conclusion, the threat to supply chain disruptions and the downstream impact to patient harm as a result of continued sterilization facility closures is real. It is imperative that we work together to develop solutions that balance the risks associated with current sterilization techniques and patient care needs. We must be thoughtful in how we approach this delicate balance, so we do not hit a tipping point resulting in a greater crisis.

Again, I thank the FDA for the opportunity to provide these comments and I am happy to take any questions.