Food and Drug Administration: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting Announcement
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Thank you to the FDA and advisory committee members for the opportunity to provide comments today regarding the sterilization of medical devices and its role in protecting public health. My name is Kara Mascitti and I am an infectious disease physician at St. Luke's University Health Network. In addition to my clinical role caring for patients with infections, I also serve as the Medical Director of Healthcare Epidemiology and Infection Prevention for my network.

St. Luke's University Health Network is a non-profit, regional, fully integrated, nationally recognized network providing services at ten hospitals and more than 300 sites through Pennsylvania and New Jersey. St. Luke's averages 72,000+ admissions and 279,000+ emergency room visits annually.

As an infectious disease physician, I know firsthand the importance of ensuring that physicians have access to sterilized products for patient care. Every single patient that is admitted to one of our hospitals or visits one of our emergency rooms requires at least one sterile product as part of their medical care - whether that be a needle used to draw blood for lab work; an IV to provide fluids; antibiotics and other essential medications; a tube to provide nutrition to a neonate; or a stent to treat a heart attack. The recent closures of sterilization facilities have not impacted St. Luke's thus far in terms of our supply chain of these products. Other systems throughout the country, however, are not as fortunate and have reported disruptions of such critical, life-sustaining supplies such as intrauterine catheters, tracheostomy tubes, and surgical staplers to name a few. As a result, they've had to allocate additional time, labor and financial resources to sourcing alternatives so that they can continue to offer patients the highest quality of healthcare possible. St. Luke's may not be so fortunate in the future if this trend continues.

I am concerned that should sterilization facility closures continue throughout the country without adequate warning or contingency planning, that patient safety will be at risk and unnecessary patient harm will occur. Additionally, this would almost certainly translate into increased healthcare costs and strain a healthcare system in the US that is already under financial pressure. We must work together to find a solution that appropriately balances the risks associated with ethylene oxide sterilization and the urgent needs of sick patients in our country. I applaud the FDA for initiating this discussion and thank you for inviting me to share the provider and health system perspective. My comments today focus on three main points:

- One, internalization of sterilization by hospitals and health systems would be prohibitive in terms of costs and logistics;
- Two, inadequate sterilization would be catastrophic for patient care and threaten modern medicine as we know it; and
- Three, changes to sterilization methods must occur in a coordinated and systematic manner to minimize unintended consequences.

Point #1: Internalization of sterilization by hospitals and health systems would be prohibitive in terms of cost and logistics.

St. Luke's has ethylene oxide sterilization capability at two of our ten hospitals that is used in a very limited capacity for the sterilization of some of our gastrointestinal scopes as well as supplies for the intensive care unit, radiation oncology, and cardiac catheterization lab. While we have other methods of sterilization in our network including steam and gas plasma, these specific products are not validated for, appropriate for, or stable with these alternative sterilization methods. To minimize ethylene oxide emissions and staff exposure, we process only full loads when possible and use a self-contained system with a 15-hour cycle of 3 hours of sterilization and 12 hours of aeration. Our annual emissions are estimated at less than 30 pounds.

Overall, our internal sterilization capabilities are miniscule compared to the number of sterile products we use daily for patient care. If we were forced to sterilize every product used within our health system ourselves:

- It would be cost prohibitive to build the necessary infrastructure and hire and train the necessary staff to operate such a facility.
- It would create additional risk to us as the healthcare provider, as it would shift the liability of ensuring product sterility from the manufacturer to our hospitals.
- It would increase the regulatory burden on our hospitals which would lead to an additional increase in costs and legal resources to ensure compliance.

I imagine that the impact would be even greater for systems that do not currently have sterilization capabilities, or community facilities that are often the only healthcare provider for their vulnerable, rural or underserved populations. For them, the financial burden would likely be so great that it would threaten their ability to remain operational and provide care at all.

I am also concerned that moving away from a centralized sterilization system and fragmenting sterilization would lead to increased patient risk. Currently, a centralized process of sterilization ensures a high level of quality control, reliability, and product confidence. In a decentralized system every hospital would be left vulnerable in terms of its ability to provide consistent patient care should sterilization operations at a facility be compromised or need to be temporarily shut down, as in the case of a natural disaster, inclement weather or highly infectious disease outbreak. While contingency plans might be feasible for larger systems to develop or implement, our smaller and more lean systems may not be able to support such backup plans and therefore would have to temporarily cease patient care if sterile products were not available.

Finally, while our goal is to decrease global ethylene oxide emissions, I worry that a decentralized process might actually increase these. While emissions would occur in smaller pockets spread across larger geographic areas, diluted if you will, we might actually see an increase in overall emissions due to more inefficient processing.

Point #2: Inadequate sterilization would be catastrophic for patient care and threaten modern medicine as we know it.

As a healthcare provider, I never want to be in a situation where I question the sterility or safety of a product that I am using for a patient. Or worse, I never want to be in a situation where I cannot care for a patient due to a shortage of a critical product. As a resident in Internal Medicine I had the privilege to work in an underserved public hospital in Botswana. I witnessed firsthand how our ability (or inability) to care for sick patients hinged on such basic factors as product availability. If we had no endotracheal tubes that month, patients could not be intubated and were left to die of respiratory failure. Unfortunately, if the sudden closure of sterilization facilities continues, this may become a reality in our own country and threaten modern medicine as we know it.

The potential risk to patients is real. We cannot risk placing potentially contaminated devices into, and causing infection, in already compromised, sick patients whose loved ones have entrusted us to heal them. We cannot risk cancelling surgeries and other necessary medical procedures, or being unable to care for patients in emergent situations, because we lack the necessary supplies. Product contamination or lack of availability of sterile medical devices will absolutely lead to prolonged hospital stays, increased costs of care, worsening patient outcomes and even unnecessary death.

In essence, sterility issues and product disruptions could completely disrupt healthcare as we know it.

Point #3: Changes to sterilization must occur in a coordinated and systematic manner to minimize unintended consequences.

As a physician and an epidemiologist, I understand the importance of not only caring for the sick, but also protecting the health of and preventing illness in our general population. It is crucial to ensure that in our efforts to help and heal people, we are not causing unintended harm to others. I believe the answer to our current situation is to work together to find the appropriate balance between the risks associated with current sterilization techniques and the medical needs and safety of the sick in our communities. However, that balance cannot be struck overnight.

A coordinated and systematic approach to addressing sterilization concerns is necessary to minimize disruptions to supply chain and prevent potential downstream harm to patients. To achieve this, it is imperative that we:

- Approach sterilization of medical devices collaboratively such that all stakeholders have a seat at the table and work together to develop a cohesive strategy.
- Align our future state to incorporate federal and state requirements across all appropriate agencies, marrying environmental concerns with patient safety standards.
- Permit sufficient time for change and compliance.

- Allow existing entities to continue current sterilization methods as they work toward instituting change.

In summary, I urge the FDA to continue to work collaboratively with all stakeholders to develop a coordinated, cohesive, and systematic approach to addressing the concerns with ethylene oxide while carefully considering the unintended negative consequences that sterilization facility closures would have on patient care. We can change, and perhaps *should* change, the status quo, but we must be thoughtful in how we make the change.

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