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United States Senate
WASHINGTON, DC 20510–4704

February 3, 2014

The Honorable Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

Last week, news reports highlighted a recent cluster of infections caused by carbapenem-resistant *Escherichia coli* (CRE), which were linked to the use of contaminated medical devices, known as duodenoscopes, at a well-known Seattle medical center, Virginia Mason. While outbreaks of CRE have occurred across the country, world class surveillance and timely engagement by the hospital and the Washington State and Seattle & King County Departments of Health identified the cause of this unusual outbreak and worked quickly to minimize its spread.

CRE infections are serious, with fatality rates as high as 40-50%. In Seattle, at least 32 patients were infected with CRE via duodenoscope contamination, and though 11 of these patients died, it remains unclear whether CRE was the cause. Without the rapid and conscientious responses of Virginia Mason and the state and local health departments, the public health impact could have been much worse. Other recent outbreaks associated with the use of duodenoscopes occurred in Pittsburgh and Chicago, with dire consequences.

Due to their complicated and intricate design, duodenoscopes are harder to clean and disinfect than many reusable medical devices. Yet in Seattle, parallel assessments of duodenoscope reprocessing procedures by both the Washington State Department of Health and the Centers for Disease Control (CDC) found that duodenoscopes used by Virginia Mason routinely failed to pass testing for pathogenic bacteria, despite strict adherence by the hospital staff to the manufacturer's labeling. In some cases, cleaning measures recommended by the manufacturer were insufficient to remove debris and soil, forcing medical staff to adopt more aggressive cleaning techniques. These findings indicate that – even when providers carefully follow manufacturers' labeling regarding cleaning and disinfection of duodenoscopes – contamination still poses grave risks to patients.

The Food and Drug Administration (FDA) issued a draft guidance in 2011 entitled "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," which updated prior guidance on the reprocessing of reusable medical devices. This

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update is an important step forward in addressing antibiotic resistant infections caused by reprocessed duodenoscopes, bolstering criteria used to evaluate product labeling and reprocessing procedure validation measures. I appreciate these efforts to improve the safety of reusable medical devices.

In light of the infections in Seattle and other communities across the country, I am writing to urge the FDA to finalize this guidance and provide health care professionals with updated best practices for reusable medical devices as soon as possible. In doing so, FDA should focus on the unique issues surrounding the reprocessing of complex devices, such as duodenoscopes. The FDA should also consider whether more robust post-market surveillance, beyond that discussed in the draft guidance, is appropriate given the nature of these devices and recent outbreaks.

FDA also should work closely with manufacturers of duodenoscopes and other complex reusable devices to ensure that product labeling reflects the most recent available knowledge regarding effective reprocessing techniques. Because that process will take some time, FDA also should consider whether additional safety information should be communicated to providers, patients and other stakeholders in the meantime.

Your ongoing collaboration with FDA's sister agency, the CDC, is also critical to ensure a comprehensive approach to preventing and detecting future outbreaks.

While recognizing that many stakeholders have a part to play in combatting device-borne infection, the FDA plays a critical role. I urge you to take the steps identified above as soon as possible.

Sincerely,

Patty Murray

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United States Senator

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