United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

April 3, 2017

Karl Watanabe
President and Chief Financial Officer
Olympus Corporation of the Americas
3500 Corporate Parkway, P.O. Box 610
Center Valley, PA 18034

Dear Mr. Watanabe:

According to news reports, a medical device called a closed-channel duodenoscope manufactured by your company was recently linked to an outbreak of antibiotic-resistant infections that sickened at least five patients, one of whom died. This tragic incident is particularly alarming because your company recalled and reportedly fixed the device in question after an investigation by my staff revealed a dangerous flaw in the design of Olympus duodenoscopes that could put patient safety at risk. I write to you today to request information in order to assess whether repaired Olympus closed-channel duodenoscopes are safe, and to understand whether the federal oversight of medical device safety in the United States is operating as it should.

I first became alarmed about the safety of closed-channel duodenoscopes in January 2015 after press reports revealed that multiple patients at Virginia Mason hospital in Seattle, Washington had contracted a dangerous antibiotic-resistant infection after undergoing a procedure with the device. At the time, I directed my staff on the U.S. Senate Health, Education, Labor, and Pensions ("HELP") Committee to investigate what went wrong, and in January 2016, I released the report *Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients*. My report revealed that closed-channel duodenoscopes had a design flaw that allowed dangerous antibiotic-resistant bacteria to linger in the device even when cleaned according to the manufacturer's instructions. The report linked the device to at least twenty-five different outbreaks of antibiotic-resistant infections that sickened at least 250 patients worldwide. Nineteen of those outbreaks were traced specifically to Olympus duodenoscopes.

My investigation found not only that the Olympus duodenoscope suffered from a serious design flaw, but also Olympus and other device manufacturers failed to submit timely and thorough medical device reports as required by law. Additionally, Olympus knew of two independent reports demonstrating that the TJF-Q180V model scope could not be cleaned effectively between uses, but did not alert patients and doctors in the United States until two years later. Documents released by your company in response to court proceedings reveal that Olympus was urged by some of its own staff to issue a recall or a safety alert in the United States, but the company failed to do either, and hospitals and patients across the country, including Virginia Mason Hospital in Seattle, experienced deadly outbreaks of antibiotic-resistant infections as a result.

My report also identified several regulatory failures by hospitals and the Food and Drug Administration (FDA) that contributed to the delay in identifying the risk the duodenoscope posed to patient safety. The report made a variety of recommendations to device manufacturers, hospitals, and the FDA to ensure rigorous compliance with laws and regulations designed to protect patients and to and strengthen oversight of medical devices.

After the report was released, your company recalled more than 4,000 closed-channel duodenoscopes used in hospitals in the United States in order to fix the design flaw that trapped bacteria and prevented effective cleaning. Patients and doctors were assured that so long as the device was cleaned properly, repaired closed-channel duodenoscopes would no longer spread deadly bacteria from one patient to another. However, reportedly, the device involved in the most recent outbreak had undergone the same or similar modifications as the Olympus duodenoscopes in the United States, raising questions about whether the repairs are working correctly.

It is essential that patients and doctors are confident that the devices used in medical procedures are safe, and following the tragic impacts outbreaks have had on patients and families in my home state and across the nation, I remain absolutely committed to ensuring rigorous oversight of medical device safety. To that end, I request that you provide following information no later than April 17.

1. Unredacted copies of all medical device reports or adverse event reports sent by Olympus to the FDA regarding the TJF-Q180V, TJF-Q180V-2, or any other closed-channel duodenoscope models from February 1, 2016 until today.

2. Copies of all documents from February 1, 2016 until today that reference antibiotic-resistant infections and any duodenoscope.

3. Validation data demonstrating that *repaired* TJF-Q180V duodenoscopes can be reprocessed effectively.

Thank you in advance for your cooperation. If you have any questions related to this request please contact Carly Rush or Remy Brim with the HELP Committee at 202-224-3254.

Sincerely,

Patty Murray
Ranking Member, Senate Health, Education
Labor, and Pensions Committee

Cc: Lamar Alexander, Chairman