United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

June 8, 2015

Karl Watanabe
President and Chief Financial Officer
Olympus Corporation of the Americas
3500 Corporate Parkway, P.O. Box 610
Center Valley, PA 18034-0610

Dear Mr. Watanabe:

As questions continue to arise regarding your company's actions to adequately protect patients treated with your duodenoscopes, I write to seek more information and express my serious and growing concern. As you are aware, between late 2012 and January 2014, Virginia Mason hospital in Seattle, Washington experienced an outbreak of deadly carbapenem-resistant Enterobacteriaceae (CRE) infections which were subsequently traced to duodenoscopes manufactured by Olympus. In all, 32 individuals were infected with CRE, an additional 7 people developed a separate *E coli* infection, and 18 of those who developed infections later died.[1]

In addition, multiple cases of CRE infections traced back to Olympus duodenoscopes have now been confirmed at two other hospitals in 2014, as well as a series of CRE infections involving an Olympus duodenoscope in Florida in 2009. In all, the Food and Drug Administration (FDA) confirmed at the recently convened Advisory Committee Meeting of the Gastroenterology-Urology Devices Panel that there have been at least nine hospital outbreaks of multidrug-resistant infections traced to duodenoscopes in the United States, and that six of those outbreaks are traceable to scopes manufactured by Olympus.[2] Olympus is reported to have told health care professionals in February that the company was aware of 95 complaints of infection in patients who had undergone procedures with TJF-Q180V, the "closed elevator" duodenoscope sold since 2010, without Olympus seeking FDA approval or clearance before marketing.[3]

Overall, FDA has informed me it received 139 separate reports of contamination or infection related medical device reports, or adverse event reports involving duodenoscopes between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone.[4] Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus (85 percent market share of duodenoscopes), Fujifilm, and Pentax Medical.[5]

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[1] Many of the individuals who died suffered from serious illnesses and thus, those deaths may not be the direct result of the CRE infections.
[2] FDA Executive Summary, Meeting of the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee, pp.14-15.
[3] Chad Terhune and Melody Petersen, "Scope maker Olympus faces scrutiny over patient deaths, infections" Los Angeles Times, March 1, 2015.
[4] Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.
[5] Id.

I have become increasingly concerned by the failure of Olympus to proactively warn patients and providers in the United States of the potential for infections. It is my understanding that in November of 2013, at the invitation of officials at Virginia Mason concerned about the CRE infections at the hospital, an endoscopy support specialist from Olympus spent two days at the hospital and validated that the hospital was properly cleaning Olympus duodenoscopes between uses. That review by Olympus staff demonstrated that "endoscope reprocessing procedures at [the hospital] were above the industry standard, and all technicians performed manual endoscope cleaning in a manner consistent with manufacturer guidelines."[6] Olympus officials subsequently removed a number of the scopes in use at Virginia Mason for repair.

Thus, as early as November 2013, it appears that Olympus knew or should have known that even in cases where hospital staff were carefully executing Olympus' instructions for cleaning, duodenoscopes continued to be contaminated with CRE and other bacteria. Further, it strongly suggests that Olympus knew its current cleaning and reprocessing standards were insufficient, and that use of the company's duodenoscopes, particularly the TJF-Q180V model sold since 2010 and featuring a "closed elevator," were placing patients undergoing procedures at risk of multi-bacteria resistant infections. Moreover, although medical device manufacturers are required to file reports of possible safety risks within 30 days, press reports suggest that Olympus did not even file the required Medical Device Report with the FDA in connection with the Virginia Mason infections until August 2014.[7] And as recently as February of this year, more than a year after the Virginia Mason CRE outbreak, I understand that the Olympus manager of infection control told a meeting of health care professionals that "endoscopes reprocessed properly pose virtually no risk of patient-borne or environmental organisms."[8]

This stands in marked contrast to the actions taken by Olympus in Europe. According to press reports, as early as January 2013, Olympus is reported to have issued "important safety advice" to European hospitals instructing staff to use a specific brush supplied by Olympus to clean duodenoscopes. This action is reported to have been taken following a series of infections at Erasmus University in Rotterdam in early 2012. Dr. Margreet Vos provided testimony at the recent FDA Advisory Committee meeting that in 2012 independent reviewers found bacteria present in reprocessed Olympus scopes.

Again in August 2014, Olympus is reported to have sent a second safety alert to European hospitals that asked hospital staff to sign and return an acknowledgement that the warning had been shared with staff. No such alert was sent in this country until February of this year, and the cleaning brushes apparently sent to European hospitals in early 2013 were not provided to U.S. hospitals until last month.

These facts build upon my existing concerns regarding Olympus' 2010 failure to seek clearance or approval from the FDA prior to marketing TJF-Q180V, the "closed elevator" duodenoscope at issue in a number of the infections. I find it very troubling that when Olympus

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[6] See Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.
[7] Peter Eisler, "Reports to Feds on deadly bacteria outbreaks arrived late" USA Today, April 15, 2015.
[8] Chad Terhune and Melody Petersen, "Scope maker Olympus faces scrutiny over patient deaths, infections" Los Angeles Times, March 1, 2015.

became aware of increased reports of infections linked to the TJF-Q180V, the company appears not to have taken additional steps to alert health professionals and regulators in the United States to the risks this particular device posed. Moreover, when asked by the FDA in the spring of 2014 to provide the data that validated that Olympus duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Olympus (as well as Fujifilm and Pentax Medical) was unable to do so through two rounds of testing.[9] New cleaning guidance was finally approved by FDA in March 2015.

I find it similarly troubling that Olympus (as well as Fujifilm and Pentax Medical) declined to participate in the subsequently convened FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures," despite manufacturing 85 percent of the scopes used in these procedures. But at the same time, the company was apparently able to have representatives present at two large professional conferences in Washington, D.C. that same week.[10] Just days before the FDA Advisory Panel meeting, Olympus announced that the company was reducing its expected earnings forecast for this year as a result of an ongoing investigation by the Department of Justice into potential violations of the Anti-Kickback Statute, and last week Olympus announced that it is under investigation by the United States Attorney for the District of New Jersey relating to the duodenoscope infections.[11]

Even with enhanced cleaning procedures adopted earlier this year, these necessary and important devices must be handled with extreme care to help prevent infections. At the FDA panel meeting, two-thirds of hospitals reported that scope cultures were positive for organisms after reprocessing. While representatives of Virginia Mason explained that the hospital has established a protocol requiring that, after a duodenoscope has been thoroughly cleaned and reprocessed, it is cultured for bacteria, this process requires a 48-hour waiting period between uses of a scope, and has required the hospital to purchase additional scopes.[12] Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.[13]

I am committed to ensuring that the families impacted by these tragic outbreaks in Washington State and across the country get answers and accountability. In order to better understand the timeline of events and your company's response to reports of infections related to duodenoscopes manufactured by Olympus, including the TJF-160, TJF-Q180V-1 and TJF-Q180V-2, please provide the following information by June 19, 2015.

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[9] "FDA Moves to Ensure Scope Safety", Los Angeles Times, March 15, 2015; Information provided by Dr. Vos to the Advisory Committee panel indicated that Olympus failed to provide requested information regarding the efficacy of cleaning procedures to the Dutch National Institute of Public Health and the Environment.

[10] Chad Terhune, "Scope maker defends device design" Los Angeles Times, May 19, 2015.

[11] Olympus News Release, Recognition of Extraordinary Loss Due to the Investigation by the U.S. Department of Justice Against Our Subsidiary and Notice of Difference Between Consolidated Earnings Forecast and Actual Results, May 8, 2015; Olympus Financial Results filing, Consolidated Financial Results for the Fiscal Year Ended March 31, 2015; Chad Terhune and Melody Petersen "Justice Department investigates scope maker Olympus over superbug outbreaks" Los Angeles Times, May 28, 2015.

[12] FDA Executive Summary, Meeting of the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee p. 15.

[13] Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

1. Copies of all alerts, cleaning guidance, safety advice or warnings provided to any hospital or regulatory agency, foreign or domestic, mentioning any scope manufactured by Olympus used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.

2. Unredacted copies of all medical device reports or adverse event reports sent by Olympus to FDA regarding the TJF-Q180V-1 and TJF-Q180V-2 or any other scope used in Endoscopic Retrograde Cholangiopancreatography Procedures between 2005 and present.

3. Copies of all documents between 2010 and present that reference or refer to CRE or other infections and any endoscope, including any duodenoscope, manufactured by Olympus.

Sincerely,

Patty Murray

Senator Patty Murray
Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee