United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

June 8, 2015

Christopher Burton
President of the Americas Region
Pentax Medical
3 Paragon Drive
Montvale, New Jersey 07645

Dear Mr. Burton:

As questions continue to arise regarding Pentax Medical's actions to adequately protect patients treated with duodenoscopes, I write to seek more information and express my serious and growing concern. As you are likely 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 Corporation. 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]

Multiple cases of CRE infections traced back to duodenoscopes have now been confirmed at two other hospitals in 2014. In fact, the Food and Drug Administration (FDA) stated at the recently convened Advisory Committee Meeting of the Gastroenterology-Urology Devices Panel that there have been at least nine hospital outbreaks of multi-drug resistant infections traced to duodenoscopes in the United States, two of which are traceable to scopes manufactured by Pentax Medical.[2]

Overall, FDA has informed me that 139 separate reports of contamination or infection-related medical device reports, or adverse event reports involving duodenoscopes were received between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone.[3] Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus, Fujifilm and your company.[4]

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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] Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.
[4] Id.

I have become increasingly concerned by the failure of the three manufacturers to proactively warn patients and providers of the potential for infections. As early as January 2013, more than 38 patients were infected with CRE at a hospital near Chicago, Illinois that was linked to duodenoscopes manufactured by Pentax Medical.[5] By September 2013 the Center for Disease Control and Prevention (CDC) had notified the FDA of the possible connection between multi-resistant bacteria hospital infections and duodenoscopes even when reprocessed according to the manufacturer's instructions.[6] At approximately the same time, in November of 2013, an Olympus endoscopy support specialist found that Virginia Mason, which was attempting to contain a CRE outbreak, was properly reprocessing duodenoscopes stating "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."[7] Thus, it appears that duodenoscope manufacturers should have been aware by at least late 2013 of the very real risk of multi-drug resistant infection from procedures using duodenoscopes even when cleaned according to instructions provided by the manufacturers.

I am not aware of that any additional steps were taken by Pentax Medical that may have alerted health professionals to the risk of infection even when properly cleaned. Moreover, when asked by the FDA in the spring of 2014 to provide the data that validated that Pentax Medical's duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Pentax (as well as Olympus and Fujifilm) was apparently unable to do so through two rounds of submissions. It appears that no updated cleaning guidance has been issued by Pentax for these scopes. Pentax Medical, in addition to Olympus and Fujifilm, also declined to participate in the May 14-15, 2015 FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures" despite manufacturing the scopes used in these procedures.[8]

Even with enhanced cleaning procedures and more rigorous validation, it is clear that 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.[9] 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. Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.[10]

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[5] "Pentax scope data are sought," Los Angeles Times, March 31, 2015.

[6] Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

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

[8] Pentax Medical was apparently able to have representatives present at two large professional conferences in Washington, D.C. despite not attending the FDA Adivsory Panel meeting. *See* "Scope maker defends device design" Los Angeles Times, May 19, 2015.

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

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

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 Pentax's response to reports of infections related to duodenoscopes manufactured by Pentax Medical, including the ED-3490 TK, please provide the following information by June 19, 2015.

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 Pentax Medical used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.

2. Unredacted copies of all medical device reports or adverse event reports sent by Pentax Medical to FDA regarding the ED-3490 TK 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 Pentax Medical.

Sincerely,

Patty Murray

Senator Patty Murray
Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee