United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

June 8, 2015

Masataka Akiyama
President and Chief Executive Officer
Fujifilm Medical Systems USA, Inc.
419 West Avenue
Stamford, CT 06902

Dear Mr. Akiyama:

As questions continue to arise regarding Fujifilm Medical Systems USA's (Fujifilm) 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 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, including one outbreak of CRE in 2014 traceable to scopes manufactured by Fujifilm.[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, Pentax Medical and your company.[4]

---

[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. 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.[5] 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."[6] 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.

While it has been reported that Fujifilm submitted a timely adverse incident report to the FDA related to a May 2014 infection linked to a Fujifilm ED 530 XT duodenoscope, when asked by the FDA in the spring of 2014 to provide the data that validated that Fujifilm's duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Fujifilm (as well as Olympus and Pentax Medical) 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. Fujifilm, in addition to Olympus and Pentax Medical, 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.[7]

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.[8] 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.[9]

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

---

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

[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] Fujifilm 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.

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

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

understand the timeline of events Fujifilm's response to reports of infections related to duodenoscopes manufactured by Fujifilm, including the ED 530 XT, 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 Fujifilm used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.

2. Unredacted copies of all medical device reports or adverse event reports sent by Fujifilm to FDA regarding the ED 530 XT 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 Fujifilm Medical Systems.

Sincerely,

Patty Murray

Senator Patty Murray
Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee