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NEWS

Olympus chose not to alert US doctors of infections linked to its duodenoscopes

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Executives at Olympus chose not to alert its US customers to the fact that dozens of serious infections had been linked to its duodenoscopes despite the warning being issued to its European customers, a report in the *Los Angeles Times*, published 24 July, has said.[1]

Company emails filed in a Pennsylvania court as part of a patient lawsuit showed that in January 2013 an Olympus executive in the US, concerned about reports of infections in the US, asked in an email to the company's Tokyo office whether the company should alert US physicians of the potential danger.[2]

"Should [we] also be communicating to our users the information that [Olympus Europe] is communicating to their European users?" asked Laura Storms, vice president of regulatory and clinical affairs in Center Valley, Pennsylvania, in an email to Tokyo headquarters dated 31 January 2013.

In reply, Susumu Nishina, the company's chief manager for market quality administration in Tokyo, said that such an alert was not necessary because the risk was "acceptable." Nishina said that it was "not need[ed] to communicate to all the users actively" but that Storms "should communicate with the user who has asked a question."

An investigation by the US Senate released earlier this year said that Olympus was aware by early 2012 that its closed channel duodenoscopes could remain contaminated after repeated cleaning but did not inform the US Food and Drug Administration or alert hospitals, physicians, or patients in the US to the risk of infection until February 2015.[3 4] The company issued a recall of the devices in January of this year shortly before the findings of the Senate investigation were released.

Closed channel duodenoscopes are commonly used in endoscopic retrograde cholangiopancreatography to relieve blockage of the bile or pancreatic ducts. Because this procedure requires maneuvering a catheter into the ducts, these devices are more complex than standard endoscopes and have crevices and mechanisms that are difficult to clean. Infections linked to the devices are often due to antibiotic resistant organisms, such as carbapenem resistant enterobacteriaceae, and the patients are often elderly or infirm. As many as 350 infections have been linked to the devices worldwide, including at least 35 deaths in the US, the paper reported.

Olympus and its executives declined to answer questions from the *Los Angeles Times* for the story but issued a statement saying, "Patient safety is our top priority. The duodenoscope issue continues to receive the highest level of attention at Olympus, and we remain committed to working with the proper authorities and our stakeholders to understand and address the potential root causes."

Olympus America had not replied to a request for comment from *The BMJ* by the time this story was filed.

1 Terhune C. Olympus told its US executives no warning about tainted medical scopes was needed, despite superbug outbreaks. *Los Angeles Times* 25 July 2016. http://www.latimes.com/business/la-fi-olympus-scopes-emails-20160721-snap-story.html.
2 Olympus emails filed in court https://www.documentcloud.org/documents/2996071-Redacted-Olympus-Documents.html#document/p43/a309225.
3 Senate Health. Education, Labor, and Pensions Committee. Preventable tragedies: superbugs and how ineffective monitoring of medical device safety fails patients. 13 Jan 2016. www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf.
4 McCarthy M. Manufacturers failed to report infections from duodenoscopes, US investigation finds. *BMJ* 2016;352:i240. doi:10.1136/bmj.i240 pmid:26767572.