

Congress of the United States
House of Representatives
Washington, DC 20515-0533

March 23, 2015

Mark A. Miller
Vice President
Communications & Marketing Services
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley, PA 18034-0610

Via Email and Fax (484-896-7196)

Dear Mr. Miller:

Thank you to Olympus America for making medical devices that have improved the quality of life for patients. The Olympus duodenoscope, however, has been linked to multiple deaths and repeated outbreaks of antibiotic-resistant bacteria nationwide and in my district.¹ Reports indicate that even when hospitals follow Olympus' cleaning instructions, Carbapenem-Resistant Enterobacteriaceae (CRE) can still remain on the duodenoscope.² The Food and Drug Administration (FDA) has stated that the redesign of the scope in 2010 was not approved, and that Olympus has twice failed to submit data showing the scope can be cleaned reliably.³

CRE outbreaks caused by duodenoscopes also have national security ramifications. President Obama issued an executive order on September 18, 2014 stating that "combating antibiotic-resistant bacteria is a national security priority." The President directed federal agencies "to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria." In 2013, the Centers for Disease Control and Prevention (CDC) issued a report, "Antibiotic resistant threats in the United States," that called CRE an "urgent threat."

I am writing to get answers from Olympus that will help inform policymakers in formulating responses to this health and national security problem, and to get reassurance that Olympus is urgently addressing the current situation. I am also writing to inquire whether Olympus, as the market leader in these scopes, can help hospitals cope with a scope design that has led to deadly CRE outbreaks.

¹ *Scope maker Olympus faces scrutiny over patient deaths, infections*, Los Angeles Times, March 1, 2015

² *FDA to require proof that reusable medical devices can be reliably cleaned*, Washington Post, March 12, 2015

³ *FDA to require proof that new devices can be cleaned reliably*, Los Angeles Times, March 12, 2015

I request that Olympus answer the following questions:

1. What plans, if any, is Olympus pursuing to redesign its duodenoscope so that the scope can be cleaned reliably?
2. What plans, if any, does Olympus have to recall the current duodenoscope and replace it with one that can be cleaned reliably?
3. Why did Olympus not seek FDA approval of the redesign of Olympus' duodenoscope in 2010?
4. When did Olympus first learn that its duodenoscope was causing CRE infections and outbreaks? What did Olympus do with that information?
5. What alternative cleaning methods, if any, does Olympus recommend that hospitals use to clean the current Olympus duodenoscope?
6. Does Olympus believe all hospitals using the Olympus duodenoscope should follow the duodenoscope surveillance protocol recently published by the CDC?⁴
7. What information does Olympus believe should be provided to patients who undergo procedures that require the Olympus duodenoscope?

The design and cleaning problems with the Olympus duodenoscope has caused CDC to issue new duodenoscope surveillance protocols to guard against CRE contamination. Many hospitals nationwide and in my district now follow these protocols, or resort to alternative cleaning methods such as gas cleaning, to address the apparent design defect in the Olympus duodenoscope. These new protocols, however, render the duodenoscope inaccessible for 24 hours, 48 hours, or more. This has now caused hospitals that have experienced CRE outbreaks from Olympus duodenoscopes to purchase even more Olympus duodenoscopes.

Hospitals initially purchased Olympus duodenoscopes with the understanding that the scopes can be used multiple times during the day and that they can be reliably cleaned. Neither assumption seems true. Olympus thus sold a product that failed to perform to its specifications.

It seems fundamentally unfair for Olympus to be selling more duodenoscopes to these same hospitals as a result of the design problems created by Olympus in the first place. Endoscopy expert Lawrence Muscarella recently stated, "In an ironic twist, the CDC protocol would likely increase sales of the devices."⁵ I would like to ask whether Olympus—as a show of good faith that the company is trying to remedy the situation—would consider donating additional duodenoscopes to hospitals that resort to alternative cleaning methods, or providing the scopes at cost without a profit, until the design or cleaning problems have been resolved.

⁴ CDC issues interim duodenoscope surveillance protocol, *Infection Control Today*, March 12, 2015

⁵ Exclusive: U.S. health officials push for stricter 'superbug' defense, *Reuters*, February 20, 2015

Thank you for your attention to this serious matter. Multiple patients in my district and nationwide have died as a result of CRE infections from Olympus duodenoscopes, and countless more have been exposed to, or fallen ill from, CRE outbreaks. Hospitals are now spending increasing amounts of money to prevent CRE outbreaks arising from an apparent design defect in the Olympus product. The antibiotic-resistant bacteria outbreaks associated with Olympus duodenoscopes also impact one of America's national security priorities. I look forward to working with Olympus and other stakeholders to resolve the current problems as soon as possible. I am also happy to meet regarding these critical issues.

Sincerely,



Ted W. Lieu
Member of Congress

cc:
Food and Drug Administration
Centers for Disease Control and Prevention

Dirty scopes investigation shines light on underreported cases in U.S.

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An investigation into patient infections from medical scopes at Huntington Hospital in Pasadena, Calif., found that more patients had been infected by bacteria on the scopes than previously reported. The latest information in a Pasadena Public Health Department report disclosed that 16 patients were infected by bacteria on the scopes, including 11 who have since died.

While it is unclear if the infection was a factor in the deaths — many of the patients had serious illnesses including cancer — the findings of the ongoing investigation show that, in general, the number of patients infected by dirty medical scopes is underreported, Lawrence Muscarella, a medical safety consultant in Montgomeryville, Pa., told *The Los Angeles Times*.

“This shows a total failure of the system, from top to bottom,” Muscarella told the newspaper.

The Pasadena Health Department’s report blamed the design of the scope used in the cases and the hospital’s infection control procedures. For example, the investigation found the hospital was using canned compressed air to dry the scopes, which is not recommended by the manufacturer or guidelines.

Huntington hospital officials said they have now changed their practices based on the findings of the report and recommendations from health officials. The Pasadena Health Department said it had found no new cases since beginning its investigation Aug. 19.

The health department report said the hospital started its own review in July after three patients were found to be infected with drug-resistant bacteria. Of the 35 possible cases the hospital was looking at, the health department concluded 15 were linked to procedures done with an Olympus Corp. scope.

The hospital continued its own investigation and found patients with procedures between July 2013 and August 2015 may have been treated with scopes infected by bacteria though not all were sickened by it.

Olympus, the leading manufacturer of gastrointestinal scopes, had recalled another one of its reusable duodenoscopes in January that was linked to outbreaks at two other Southern California hospitals, UCLA Ronald Reagan Medical Center and Cedars Sinai Medical Center. The recalled scope was not the device used in the Pasadena cases.

But the growing number of incidents like those at the Southern California hospitals has led to more attention from Congress and the Food and Drug Administration. An FDA report covering the period of Jan. 1, 2010, to Oct. 31, 2015, found that as many as 350 patients at 41 medical facilities in the United States were infected or exposed to scopes tainted by bacteria, according to CNN.

A Senate investigation released in January noted there were at least 250 scope-related infections at 25 facilities in the U.S. and Europe between 2012 and 2015. The report, "Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients," found fault with both duodenoscope manufacturers and the FDA after a 17-month lag in alerting hospitals, doctors and the public to the potential risks, HCB News reported in March.

The House Oversight and Government Reform committee has been looking into the problem as part of an inquiry led by U.S. Rep. Ted Lieu, a Democrat from California. In April, Lieu introduced two bills focusing on patient safety, including the DEVICE Act, which require manufacturers to notify the FDA about warnings issued in other countries and when they changed the design or cleaning guidelines on their devices.

Lieu's legislation would also require the FDA to regulate rapid-assessment tests used by some hospitals after cleaning the scopes to see if there is bacteria growth present.



WASHINGTON DC OFFICE

2454 Rayburn HOB
Washington, DC 20515
Phone: (202) 225-3976

LOS ANGELES OFFICE

1645 Corinth Ave, Suite 101
Los Angeles, CA 90025
Phone: (323) 651-1040

MANHATTAN BEACH OFFICE (BY APPOINTMENT ONLY)

1600 Rosecrans Avenue, 4th Floor
Manhattan Beach, CA 90266

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