

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

August 29, 2016

The Honorable John Kerry
Secretary
U.S. Department of State
Washington, DC 20520

Dear Secretary Kerry,

Reports indicate that Japanese device company Olympus Corp. knowingly failed to alert and warn American hospitals, doctors and patients about its defective medical scope, the duodenoscope. The intentional actions of Olympus killed numerous Americans by causing deadly antibiotic-resistant bacteria infections in patients across our country, including at hospitals in my district.¹ I write to ask the State Department to request Japanese authorities to investigate and prosecute Olympus and its officials for civil or criminal misconduct.

An investigation by the Los Angeles Times found that Olympus knew the design of its medical scope was causing deadly infections in patients since at least 2012, but failed to disclose this information to American hospitals, doctors, or regulatory officials. When the company was initially alerted to the device's design flaws, it only issued warnings to its European customers, failing to notify U.S. customers for the same product. In doing so, Olympus deliberately endangered the lives of thousands of American patients undergoing procedures using its medical scope and killed scores of Americans. Internal emails now reveal that Olympus executives in Japan purposely told U.S. executives to not issue warnings associated with its medical scope devices, leading to antibiotic-resistant "superbug" outbreaks, infections, and deaths in hospitals all across the country.²

The Olympus duodenoscope is commonly used in procedures called endoscopic retrograde cholangiopancreatography (ERCP) and is a flexible, lighted tube that is threaded through the mouth, throat, and stomach into the intestinal area. While Olympus has made medical devices that have improved the quality of life for patients, its duodenoscope, however, has been linked to multiple deaths and repeated outbreaks of antibiotic-resistant bacteria nationwide and around the world.³ Reports indicated that even when hospitals followed

¹ *Los Angeles Times*, July 24, 2016, "Olympus told its U.S. executives no broad warning about tainted medical scopes was needed, despite superbug outbreaks."

² *Los Angeles Times*, July 24, 2016, "Internal Olympus emails shed light on how scope maker handled superbug outbreaks."

³ *Los Angeles Times*, March 1, 2015, "Scope maker Olympus faces scrutiny over patient deaths, infections."

Olympus' cleaning instructions, Carbapenem-Resistant Enterobacteriaceae (CRE), a deadly antibiotic-resistant bacteria, can still remain on the duodenoscope.⁴

Hospitals initially purchased Olympus duodenoscopes with the understanding that the scopes can be used multiple times and that they can be reliably cleaned. That turned out to be false. Olympus thus sold a product that failed to perform to its specifications, and worse, the company intentionally led a campaign to mislead the federal government, hospitals, and patients.

According to a July 24, 2016 article in the Los Angeles Times, "as Olympus carried out its decision to not warn American hospitals, the number of patient infections linked to dirty scopes continued to climb. Overall, as many as 350 patients at 41 medical facilities worldwide were infected or exposed to contaminated scopes made by Olympus or two other companies from January 2010 to October 2015. From 2012 to 2015, investigators said that at least 141 patients in nine U.S. cities were infected."⁵

CRE outbreaks caused by duodenoscopes have national security ramifications. On September 18, 2014, President Obama issued an executive order stating that "combating antibiotic-resistant bacteria is a national security priority."⁶ The President directed federal agencies "to detect, prevent, and control illnesses and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of anti-biotic 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."⁷

The White House has also taken action with their National Strategy to Combat Antibiotic-Resistant Bacteria, which seeks to tackle the threat of antibiotic resistance at all levels and empower the nation to respond comprehensively, effectively, and efficiently to this public health crisis. Because this issue poses both health and national security risks--and because Americans have died as a result of Olympus' actions--it is imperative that the State Department coordinate with the appropriate Japanese authorities to have them investigate and prosecute Olympus. I am pleased the US Department of Justice is investigating Olympus America, but we need investigations of the Japanese parent company because that is where the order to hide and mislead was given.⁸

Thank you for your consideration.

Sincerely,



Ted W. Lieu
Member of Congress

⁴ *Washington Post*, March 12, 2015, "FDA to require proof that reusable medical devices can be reliably cleaned."

⁵ *Los Angeles Times*, July 24, 2016, "Olympus told its U.S. executives no broad warning about tainted medical scopes was needed, despite superbug outbreaks."

⁶ *The White House*, September, 18, 2014, "Executive Order – Combating Antibiotic-Resistant Bacteria."

⁷ *Centers for Disease Control*, April 23, 2013, "Antibiotic Resistance Threats in the United States, 2013."

⁸ *Los Angeles Times*, May 28, 2015, "Justice Department Investigates Scope Maker Olympus over Superbug Outbreaks."