

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

December 21, 2015

The Honorable Mary Jo White  
Chair  
Securities and Exchange Commission  
100 F Street, NE  
Washington, DC 20549

Dear Chair White:

As a Member of the House Oversight and Government Reform Committee, I am deeply troubled by multiple media reports that show medical scopes made by Olympus Corporation have killed and sickened numerous patients across America, including at UCLA and Cedars-Sinai Medical Centers in my district.<sup>1</sup> An investigation by the *Los Angeles Times* alleges that Olympus knew the design of its endoscopes was causing deadly antibiotic-resistant bacterial infections in patients since at least 2012, but failed to disclose this information to hospitals or regulatory officials.

I am writing to request the Securities and Exchange Commission (SEC) investigate Olympus for fraud and violations of U.S. securities laws and other applicable laws.<sup>2</sup> I also request the SEC to refer Olympus for investigation to the relevant enforcement agencies in Japan.

The alleged evidence shows Olympus *knew* the design of its scopes used for gastrointestinal procedures could lead to infections that killed and sickened patients. According to a December 19, 2015 article in the *Times*, “[a]n investigator hired by Olympus and the hospital concluded that the scope’s design could allow blood and tissue to become trapped, spreading bacteria from

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<sup>1</sup> See, e.g., Chad Terhune and Javier Panzar, “Patient, 18, Sue Medical Scope-Maker Tied to Superbug Outbreak,” *Los Angeles Times*, February 25, 2015; Sydney Lupkin, “Scopes that Spread UCLA ‘Superbug’ were Awaiting FDA Clearance,” *ABC News*, March 4, 2015; Maggie Fox, “Two More Hospitals Report ‘Superbugs’ on Endoscopes,” *NBC News*, March 5, 2015; Elizabeth Cohen, “Deadly Super-bug Related Scopes Sold Without FDA Approval,” *CNN*, March 5, 2015; John Tozzi, “Olympus Pushed Back at FDA on Cleaning Endoscopes to Kill Superbugs,” *Bloomberg*, March 10, 2015; Peter Eisler, “Medical Scope Makers Cited for Safety Lapses,” *USA Today*, August 17, 2015; Brady Dennis, “FDA Orders Manufacturers to Study Cleaning Problems with Medical Scopes Linked to Infections,” *Washington Post*, October 5, 2015.

<sup>2</sup> The U.S. Department of Justice has launched an investigation into Olympus’ scopes. See Chad Terhune and Melody Petersen, “Justice Department Investigates Scope Maker Olympus over Superbug Outbreaks,” *Los Angeles Times*, May 28, 2015.

one patient to another.”<sup>3</sup> The investigator produced a report dated May 15, 2012 titled “Investigation Olympus TJF-Q180V Scope following detected contamination after cleaning and disinfection.”<sup>4</sup>

The report concluded the scope’s design could lead to bacterial infections and recommended Olympus take a series of actions to make the scope safer. The report specifically recommended that Olympus “[i]mprove the quality of the sealing in the scope design and minimize the amount of sealing points” and “revise especially scopes with degraded sealing, and conduct extensive sampling.”<sup>5</sup>

Instead of following the report’s recommendations, Olympus apparently embarked on a campaign of blaming hospitals rather than the scope’s design. The *Times* reported that “[a]fter each outbreak, Olympus contended that its scopes did not cause the infections and blamed the hospitals for not cleaning them properly. The company treated each case as an isolated incident, not telling the U.S. hospitals that they weren’t alone.”<sup>6</sup> As a result of Olympus’ alleged campaign of denial and deception, numerous patients have died from defective Olympus scopes.

The SEC would have jurisdiction over Olympus. Alleged misconduct by Olympus is not new to the SEC. In 2011, the SEC investigated Olympus for hiding losses from investors and making fraudulent payments of hundreds of millions in advisory fees.<sup>7</sup> While Olympus stock trades on the Tokyo Stock Exchange, it also trades on NASDAQ in the form of American Depositary Receipts (ADRs) under the NASDAQ ticker symbol OCPYN. It appears Olympus in this case would be subject to the Securities Exchange Act and SEC Rule 10b-5.<sup>8</sup>

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<sup>3</sup> Chad Terhune and Melody Petersen, “How a Medical Device Maker Kept U.S. Hospitals in the Dark About Deadly Infections,” *Los Angeles Times*, December 19, 2015.

<sup>4</sup> Dr. Ir. Arjo Loeve, “Investigation Olympus TJF-Q180V Scope following detected contamination after cleaning and disinfection,” May 15, 2012.

<sup>5</sup> *Id.*, page 24.

<sup>6</sup> Chad Terhune and Melody Petersen, “How a Medical Device Maker Kept U.S. Hospitals in the Dark About Deadly Infections,” *Los Angeles Times*, December 19, 2015.

<sup>7</sup> Lindsay Fortado and Patricia Hurtado, “Ex-Olympus Chief Said to Face Questions from SEC in U.S.,” *Bloomberg*, Nov. 18, 2011.

<sup>8</sup> For example, on November 14, 2011, purchasers of Olympus ADRs filed a class action alleging violations of the Securities Exchange Act and SEC Rule 10b-5 in a fraud case. See [LawyersandSettlements.com](https://www.lawyersandsettlements.com/lawsuit/olympus-corporation-ocpny-securities.html#.VnX-djjSlow) at <https://www.lawyersandsettlements.com/lawsuit/olympus-corporation-ocpny-securities.html#.VnX-djjSlow>. See also Vincent M. Chiappini, “How American are American Depositary Receipts? ADRs Rule 10b-5 Suits, and *Morrison v. National Australia Bank*,” *Boston College Law Review*, November 11, 2011. The author concludes that issuers of ADRs are subject to SEC Rule 10b-5 if the issuer “purposefully entered the U.S. market and its regulatory system.” In this case, there is no question Olympus entered the U.S. market to sell scopes and its scopes are regulated by the FDA.

Prior to elected office, I practiced securities law in the private sector. Our securities laws and rules hold companies liable for making misleading statements or omitting material facts. Based on the above alleged facts, it appears Olympus made misleading statements or omitted material facts regarding its duodenoscopes. Medical devices account for nearly 75% of Olympus' revenue, so the potential degradation of Olympus' reputation in the medical device field as well as lawsuits and settlements and potential recalls from failed scopes would certainly be material.

While the SEC would have jurisdiction over Olympus because of its ADRs listed on NASDAQ, Japanese authorities would have jurisdiction over Olympus because its stock is listed on the Tokyo Stock Exchange. I respectfully request the SEC to also refer Olympus for investigation to the relevant enforcement authorities in Japan.

Olympus' alleged actions in this case were reprehensible and immoral. They are also likely illegal. Instead of taking responsibility and recalling or changing the design of its scopes, Olympus apparently hid information about design defects and blamed hospitals. Patients have unnecessarily died as a result of Olympus' alleged actions. I strongly urge the SEC to investigate Olympus. Thank you for your consideration.

Sincerely,



Ted W. Lieu  
Member of Congress

cc:

United States Attorney General Loretta Lynch  
Food and Drug Administration Commissioner Stephen Ostroff  
Olympus Corporation