Report: More infections from dirty scopes than estimated

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Credit: Petr Kratochvil/public domain

At least 300 patients have been sickened by life-threatening infections linked to contaminated medical scopes—more than previously estimated by federal regulators, according to figures released Friday.

Between 2010 and 2015 more than 41 hospitals worldwide, most in the

U.S., reported bacterial infections linked to the scopes, affecting 300 to 350 patients, states a memo released by U.S. Rep. Ted Lieu, D-Calif. The lawmaker stressed that those figures likely underestimate the problem since hospitals don't always test patients for the antibiotic-resistant "superbugs" that cause such infections

"I'm absolutely certain there are lots more infections out there that are not being reported just because no one is getting tested," Lieu said in an interview with The Associated Press.

Investigators for the House Committee on Oversight and Government Reform obtained the updated figures from the Food and Drug Administration as part of a year-long investigation into "superbug" outbreaks tied to the devices. A previous report by a Senate committee found 250 reports of patients sickened by contaminated scopes, though that finding came from a shorter timespan between 2012 and early 2015. Last year, the FDA reported 142 patient infections from the medical scopes made by Olympus Corp. and other companies.

The FDA came under fire in early 2015 after several high-profile outbreaks at hospitals in Los Angeles and Seattle were linked to so-called duodenoscopes made by Olympus, a Japanese manufacturer which dominates the U.S. market. The specialized fiber-optic scopes are threaded through the digestive tract to diagnose and treat tumors and other blockages of the pancreas and bile ducts. Officials at the hospitals said they had followed the manufacturers' instructions for cleaning the devices.

"It was not hospitals or doctors who weren't cleaning the devices correctly or using them correctly, it was a fault with the devices themselves," Lieu said

Lieu, who represents sections of Los Angeles, introduced two bills

Friday that would tighten regulations of reusable medical devices that require cleaning. Among other steps, companies would need to notify the FDA whenever they change the design or cleaning instructions for a device. A separate bill would require companies to scientifically confirm the effectiveness of their cleaning procedures. Sen. Patty Murray, D-Wash., released similar legislation in the Senate last month.

Despite the links to infections, the FDA previously ruled it would keep the devices on the market because they fill an important need in routine medical procedures.

The agency said late Friday it would "carefully consider" the congressional report's findings. It's already taken steps to reduce infection with the scopes, said agency spokeswoman Deborah Kotz in an emailed statement.

Duodenoscopes feature a mechanized tip with moveable instruments used to drain blockages and perform other procedures. The complex design makes the scopes extremely difficult to clean, even with mechanical processing equipment. Bodily fluids and other debris can stay in the device's joints and crevices even after cleaning and disinfection.