Superbug outbreaks: Olympus failed to report infections for 3 years, FDA says

Los Angeles Times

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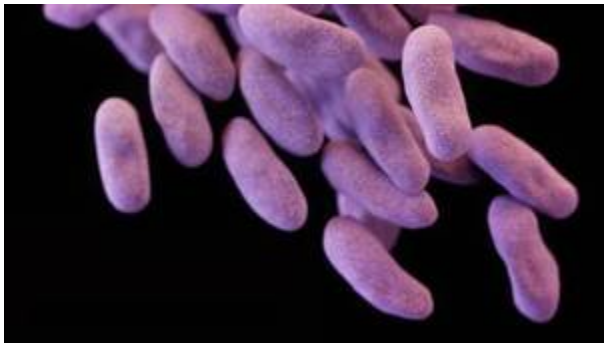
Scope maker Olympus Corp., already under investigation for several superbug outbreaks, waited three years to alert federal regulators about 16 patient infections the company learned about in 2012.

The Food and Drug Administration cited that lapse in reporting and other safety-related violations in warning letters to Olympus and two other scope manufacturers. The FDA posted the letters online Monday.

The government's findings offer further evidence that manufacturers knew about problems with these gastrointestinal scopes well before deadly infections became a major public health issue this year.

Under federal rules, companies are supposed to report potential injuries and deaths related to their devices to the FDA within 30 days.

The warning letters mark the FDA's strongest action against the device makers since an outbreak of antibiotic-resistant bacteria at UCLA's Ronald Reagan Medical Center grabbed national headlines in February.



A killer on the loose: UCLA doctors race to stop superbug outbreak and save patients

Some medical experts and federal lawmakers welcomed the agency's moves Monday. But they continued to question why regulators have taken so long to act despite earlier warnings about the risk to patients.

Rep. Ted Lieu (D-Los Angeles) called the latest revelations “disturbing” and further reason to hold congressional hearings right away.

“The fact that it took the leading scope manufacturer three years to report patient infections is flat out unacceptable,” Lieu said. “If scope manufacturers had reported infections earlier, then lives might have been saved.”

In its warning letters, the FDA cited a wide range of violations after officials inspected facilities of Olympus, Pentax Medical and Fujifilm in March and April, records show. The inspections took place in Japan and the U.S.

The agency gave the companies 15 business days from receipt of the Aug. 12 letters to respond to the violations that were found. No penalties were announced.

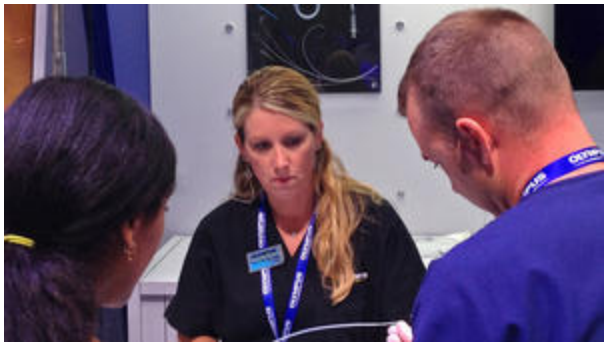
“The FDA takes these violations very seriously and will continue to monitor these firms to ensure they take appropriate corrective action,” said agency spokeswoman Jennifer Dooren.

Olympus, which controls 85% of the specialty endoscope market in the U.S., has been linked to six of the nine recent superbug outbreaks, including at UCLA where three patients died.

Mark Miller, a spokesman for Olympus, said “we are reviewing the FDA's warning letter so that we can provide the required response.”

The FDA said Olympus became aware of 16 patient infections in May 2012, but didn't report them to U.S. authorities until March 2015.

Regulators also cited two other examples of late injury reports from Olympus.



Serious infections tied to medical scopes go far beyond issues with a single device

The company became aware of one incident in November 2013 and another in June 2014. Olympus submitted data on both events to the FDA in March — a month after The Times broke the news about the UCLA outbreak.

“Failing to file a report on time places patients at serious risk unnecessarily,” said Lawrence Muscarella, a hospital safety consultant in Montgomeryville, Pa. “A three-year delay in filing a report is unreasonable, compromises safety and should have been flagged months ago.”

The 2012 incident appears to be an outbreak that occurred at a Netherlands hospital. The FDA wouldn’t comment further on the details.

As a result of the Dutch outbreak, Olympus sent an urgent warning to European hospitals in January 2013, telling them to use a special brush in cleaning the duodenoscopes. Even so, the company didn't notify U.S. hospitals or regulators.

The FDA said it didn't learn until last year of the company's European alert.

, federal regulators said the company filed reports last year regarding "fragments of cleaning brushes, stents and a dilation balloon" left inside duodenoscopes after they were cleaned.

But U.S. officials said Pentax's response failed to address how hospitals and doctors should deal with these "obstructions" that could be left inside patients and harm them.

Pentax said it's reviewing the FDA warning letter. "We take regulatory compliance very seriously," said Mark Koppel, chief medical officer at Pentax Medical Americas.

The disclosures Monday also revealed that Fujifilm has been selling a duodenoscope without the necessary FDA clearance.

The agency had previously disclosed the same problem with the latest scope model from Olympus, which has been on the market since 2010. Both companies had contended that their designs were similar enough to previous versions to avoid additional regulatory review.

The FDA disagreed and told both companies to submit applications, which are pending. The agency said it's seeking more information from Pentax on whether its devices face a similar compliance problem.

In a statement, Fujifilm said "actions have been and will continue to be taken to ensure that our products and processes meet FDA requirements."

Sen. Patty Murray (D-Washington) said the information released Monday raises more questions about FDA oversight of device makers.

"The patients and families who have been impacted deserve the facts," Murray said. "That's why I asked the FDA to conduct a full investigation into how this happened in the first place."

In addition to the ongoing FDA investigation, prosecutors with the U.S. Justice Department have sent subpoenas to all three scope makers in connection with the recent outbreaks.

Duodenoscopes are used in a procedure known as ERCP, or endoscopic retrograde cholangiopancreatography.

During the procedure, a flexible scope is put down a patient's throat to diagnose and treat problems in the digestive tract such as cancers and blockages in the bile duct. Nearly 700,000 such procedures are performed annually in the U.S.

The tip of these intricate instruments has proved to be the most difficult part to clean. Infections have occurred because dangerous bacteria became trapped around an elevator channel that holds guide wires and catheters.

Despite the risks, the FDA reiterated Monday that these scopes should remain on the market because there isn't a better alternative for patients who can benefit from their use.

Dooren, the FDA spokeswoman, said "removing these devices from the market would prevent thousands of patients from accessing this beneficial and often life-saving procedure."

Another outbreak from tainted scopes suspected at an L.A.-area hospital

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Huntington Memorial Hospital in Pasadena has notified patients who may have been infected by a contaminated medical scope made by Olympus Corp. Above, Olympus showcases its ERCP scopes at a Washington medical conference in May.

A Pasadena hospital is investigating a suspected outbreak related to the same type of medical scope tied to superbug infections across the country.

Huntington Memorial Hospital said Wednesday it had alerted health authorities about a potential link between patients who have a pseudomonas bacteria and the Olympus Corp. duodenoscopes used to treat them.

Many forms of deadly bacteria can become trapped inside the reusable devices and get passed on to future patients. Federal regulators have attributed this to a design flaw that makes the tip of these instruments hard to clean even when following the manufacturers' guidelines.

Huntington Memorial said it discovered the potential problem in June during a review of lab samples, and it has reported three patient infections to health officials so far. That number could grow as more medical detective work is done.

“We are still investigating the potential link and have engaged two nationally renowned medical research facilities for assistance,” said Dr. Paula Verrette, senior vice president and chief medical officer for quality and physician services at Huntington Memorial.

“Even though the link between the scope and bacteria is not confirmed, we alerted the affected patients about a possible link as well as reported the bacterial growth to health officials,” Verrette said.

Huntington confirmed its investigation in response to questions from The Times. The hospital declined to provide further details on the three cases or the number of patients exposed to these scopes, citing medical privacy laws.

The potential outbreak underscores the ongoing difficulty that hospitals nationwide have in cleaning and inspecting these scopes — despite intense scrutiny on these devices and the threat they may pose to patients.

The widening problem is sure to ratchet up pressure on the Food and Drug Administration and scope makers to better address concerns about patient safety. Both regulators and the companies have been under fire for ignoring earlier warnings on the infection risk.

Despite all this, federal officials have insisted that the troublesome scopes remain on the market, because there's no better alternative and many critically ill patients benefit from their use.

But some medical experts said these incidents remain underreported and the number of scope-related infections may be far higher.

“This may be a more common occurrence that's been going on for years with these scopes,” said Dr. James McKinnell, an expert on hospital epidemiology at the L.A. Biomedical Research Institute at Harbor-UCLA Medical Center. “It's sort of opening up Pandora's box as we dig in.”

Monday, FDA officials issued warning letters to Olympus and two other scope makers, Fujifilm and Pentax Medical, for a range of safety-related violations. Olympus was cited for not reporting infections to authorities in a timely manner.

The U.S. Justice Department is also investigating the superbug outbreaks and has sent subpoenas to all three scope manufacturers.

The pseudomonas uncovered at the Pasadena hospital is a common cause of infections, but some strains of the bacteria are resistant to all antibiotics. That can make it deadly for some patients.

The bacteria are similar to the CRE superbug at the center of the outbreak at UCLA's Ronald Reagan Medical Center that sickened eight patients, including three who died.

The UCLA outbreak was first reported by The Times in February. A month later, Cedars-Sinai Medical Center in Los Angeles said it had discovered four patients infected from tainted Olympus scopes.

Health officials have urged all hospitals to review their medical records to look for possible infections that have gone undetected.

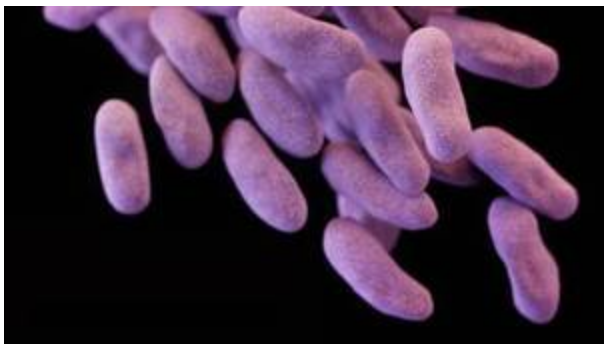
In these cases, the bacteria can be transmitted during a procedure known as endoscopic retrograde cholangiopancreatography, or ERCP.

Nationally, more than 650,000 ERCP procedures are performed each year, in which a fiber-optic scope is threaded down the person's throat to diagnose and treat problems in the digestive tract such as gallstones, cancers and blockages in the bile duct.

These instruments are not the same type used in more routine endoscopies and colonoscopies.

Olympus holds an 85% share of the U.S. market for duodenoscopes and other specialty endoscopes. A company spokesman didn't have an immediate comment on the incident in Pasadena.

In previous statements, the device maker has stressed that multiple factors can contribute to patient infections besides a flawed scope design, such as human errors during cleaning.



The Pasadena hospital said it has adopted safety measures such as quarantining disinfected scopes for 48 hours before reuse to check for any bacterial growth. The hospital didn't make it immediately clear when that step was added.

Other hospitals with outbreaks, such as Virginia Mason Medical Center in Seattle, are using that method to help protect patients.

Huntington Memorial said it explained the risk of the ERCP procedure to patients and their families. “This is a problem facing every hospital,” Verrette said. “We cannot deprive appropriate care to patients whose health issues can be relieved or addressed through the use of these scopes, but we are proceeding with an abundance of caution in our disinfecting and monitoring protocols to ensure patient safety.”

A spokesman for the Pasadena Public Health Department, which was contacted by the hospital, said it was aware of the situation and had asked for help from L.A. County authorities.

In response to the recent outbreaks, the U.S. Department of Veterans Affairs examined records to determine whether scopes sickened any of its patients. Doctors at the VA found that almost 100 patients treated with the same type of medical scope linked to the deaths of three patients at UCLA tested positive for a superbug known as CRE, or carbapenem-resistant enterobacteriaceae.

But in all but a dozen cases, the VA researchers ruled out the possibility that the patients' infections came from a possibly tainted scope, according to the study published last week.

VA officials said there didn't appear to be a wide-scale problem at its centers.

Medical scope makers cited for safety lapses

USA TODAY August 17, 2015

Elsie Florian of Munhall, PA died earlier this Spring from a superbug infection linked to a duodenoscope that was used to treat a mild intestinal problem. Her family wants people to know about the risks associated with duodenoscopes. (USA NEWS, USA TODAY)

(Photo: FDA via AP)

Federal regulators have found safety violations in the manufacturing practices of all three companies producing a specialized medical scope that has been linked to deadly superbug outbreaks at U.S. hospitals — a precursor to possible legal action against the firms.

The Food and Drug Administration revealed Monday that it issued warning letters Aug. 12 to Olympus, Pentax and FujiFilm for violating an array of manufacturing and quality control standards meant to ensure the safety of their duodenoscopes. The FDA also cited Olympus and Pentax for failing to properly notify the agency after the companies learned that infections had been linked to their scopes.

Additionally, the agency raised concerns that FujiFilm and Pentax may not have obtained proper regulatory clearance for their duodenoscopes before putting them on the market — a problem for which Olympus, which makes about 85% of the duodenoscopes on the U.S. market, already has been cited.

The warning letters are the most sweeping action taken by the FDA since USA TODAY first reported in January that duodenoscopes had been linked to superbug outbreaks that have sickened scores of patients and killed more than a dozen. The scopes, which doctors run down patients' throats to treat gallstones, tumors and other blockages of the bile and pancreatic ducts, are used about 650,000 times a year nationwide.

“The FDA takes these violations very seriously and will continue to monitor these firms to ensure they take appropriate corrective action,” FDA spokeswoman Jennifer Dooren said in a statement.

The warning letters, based on inspections of all three manufacturers’ production facilities, are the first step toward formal legal action, setting strict timelines for the companies to address the problems cited. Failure to correct the problems can lead to administrative orders, fines and, ultimately, federal lawsuits.

Olympus spokesman Mark Miller said in a written statement that the company is “reviewing the FDA's warning letter so that we can provide the required response in a timely manner.”

Pentax said in a statement that it also would respond to the FDA in the required timeframe. “We consider these issues to be of utmost importance,” Chief Medical Officer Mark Koppel said.

FujiFilm said in a statement that “actions have been and will continue to be taken to ensure that our products and processes meet FDA requirements, and pose no risks to … health and safety.”

Since USA TODAY’s ongoing investigation initially identified duodenoscope-associated superbug outbreaks in Pittsburgh, Chicago and Seattle, additional clusters of infections have been tied to the devices at hospitals in Los Angeles, Philadelphia, Milwaukee, Worcester, Mass., and other cities. Many of those cases involve a bacteria known as CRE, which has mortality rates of 40% or more.

In a story published this month, the newspaper found that many more cases probably go unreported, leaving public health officials with no clear understanding of how widespread the problem may be.

Medical investigators have traced the infections to bacteria that get trapped at the tip of the scopes, in a mechanism used to control small tools that can trim tissue or install tiny stents to open blocked intestinal ducts.

The FDA warned in February that the contamination can remain even if duodenoscopes are cleaned properly, allowing the bacteria to spread from patient to patient as the devices are reused. However, the agency has not sought to halt use of the scopes, noting that infection risks

remain relatively low and duodenoscopes remain the safest, least-invasive way to treat potentially deadly conditions.

In its new letters to the three scope manufacturers, the FDA shows growing concern about whether they met requirements for assessing the devices' safety before putting them on the market — and whether at least two of those companies properly disclosed the infection problems once they came to light.

"The FDA's actions appear now to be suggesting that this problem is much bigger than they originally thought," says Lawrence Muscarella, a Pennsylvania health care consultant who advises hospitals and medical device manufacturers on safety issues. "It seems like they're kind of working backwards a bit — as each new shoe drops, we seem to be learning that this should have been getting more attention earlier."

Among the issues:

• The FDA appears increasingly concerned about whether the manufacturers got proper regulatory clearance for their duodenoscopes before they were put on the market. All three claimed their scopes were substantially equivalent to similar devices already in use, so they did not obtain a new clearance, known as a 510K. This year, the FDA said Olympus should have gotten a new 510K clearance for its latest scope, and now it cites FujiFilm for the same problem. The agency asked Pentax for more information to determine whether that company needed a new clearance for its scopes.

• Olympus and Pentax are cited for failing to file required reports with the FDA when they first became aware that their scopes might have contamination problems. Olympus was faulted for waiting until this year to report a 2012 superbug outbreak that was linked to its duodenoscopes — an apparent reference to a reporting lapse that USA TODAY first revealed this year.

• All three manufacturers were cited for problems in their production processes. Based on inspections of the companies' facilities, the FDA noted lapses in quality controls and systems for assessing and testing the safety of their duodenoscopes. The agency also raised concerns about the companies' approaches to validating the cleaning and disinfection protocols issued for their devices.