FDA wants more info on scopes linked to "superbug" outbreaks (Update)

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This undated file photo provided by the U.S. Food and Drug Administration shows the tip of an endoscopic retrograde cholangiopancreatography (ERCP) duodenoscope, attached to a long tube, not shown. Federal health officials will meet in May to review problems with the design and cleaning of the specialized medical instruments linked to at least two recent "superbug" outbreaks. (AP Photo/U.S. Food and Drug Administration, File)

Federal health officials issued multiple announcements Thursday aimed at addressing growing safety concerns about medical scopes that have

been linked to several recent "superbug" outbreaks.

The Food and Drug Administration released stricter guidelines for manufacturers of reusable medical instruments, including specialized endoscopes used in about a half-million U.S. medical procedures each year.

For the first time the FDA is asking manufacturers to submit scientific data showing that their devices can be safely disinfected. FDA officials acknowledged that previous agency guidelines from 1996 made no such request from companies.

"Rather they could attest that they had completed or would complete the validation prior to marketing," said Dr. William Maisel, director of FDA's medical device center.

Additionally, the agency announced a two-day meeting for mid-May to gather expert opinion on improving the design and regulation of the so-called duodenoscopes. The specialized endoscopes consist of a flexible fiber-optic tube that is inserted down the throat, through the stomach and small intestine to diagnose and treat conditions in the pancreas and bile ducts.

The government announcements come amid escalating criticism of the FDA's oversight of the hard-to-clean devices, which have been linked to sometimes fatal outbreaks of antibiotic-resistant bacteria at several hospitals. Last week 10 members of Congress asked the FDA to answer questions about the devices, including how the agency reviews manufacturers' cleaning instructions.

The FDA had been working on the new device guidelines for years and previously issued a draft version of them in 2011. The agency's chief scientist, Dr. Stephen Ostroff, told reporters that the FDA "accelerated

that pace because of the recent episodes."

In the last month, two Los Angeles hospitals have reported superbug infections in patients despite following manufacturer's cleaning guidelines. The duodenoscopes' complex design—intended to help physicians drain fluids in the body—also makes the instruments extremely difficult to clean. Bodily fluids and other particles can stay in the device's crevices even after cleaning and disinfection.

In the first case, seven patients at Ronald Reagan UCLA Medical Center contracted an antibiotic-resistant strain of bacteria after undergoing endoscopic procedures with a device made by Olympus Corp. Two patients died from the infection. Last week another Los Angeles Hospital, Cedars-Sinai Medical Center, reported that four patients were infected with the same superbug after being treated with the same Olympus scope.

Previously the FDA recommended hospitals follow manufacturers' instructions for disinfecting devices, which typically involves the use of germ-killing disinfectants and manual or machine-assisted processing. But after the first of the two recent outbreaks, the FDA acknowledged that those instructions may not fully disinfect the devices.

FDA officials said Thursday they are working to see how the devices could be improved, but stressed that the FDA cannot force manufacturers to redesign products.

Additionally, outside experts said it could take years before any updated devices actually reach the market.

"Unfortunately, it's going to take manufacturers some time to design a different way to do this," said Chris Lavanchy, engineering director at the ECRI Institute, which studies medical product issues. "And then it's

going to take the FDA time to confirm that it's a safer approach."

Some hospitals have already adopted extra cleaning procedures, including sterilizing scopes with toxic ethylene oxide gas. Other steps include quarantining the scopes after use and performing laboratory testing to identify any dangerous bacteria.

The FDA and the Centers for Disease Control and Prevention issued interim guidelines on laboratory culturing for hospitals on Thursday.

The technique has become more common in Europe, Australia and elsewhere, but it is more expensive than current U.S. practice. Experts say regular culturing of equipment would require U.S. hospitals to purchase larger inventories of scopes that can be cycled in and out of use. One duodenoscope can cost about $40,000.

Contamination problems have been reported with devices made by all three U.S. manufacturers of the devices: Olympus, Pentax Medical and Fujifilm.

Despite these problems, regulators stressed that using the devices is essential for treating tumors, gallstones and other blockages around the pancreas and bile ducts.

"It is by far the lowest-risk way to diagnose and treat these very serious medical problems," Ostroff said. "Therefore it's essential that we examine this problem from A to Z until we come up with solutions that will enhance the safety margin associated with duodenoscopes."

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