FDA knew of design flaw in scope linked to UCLA superbug

February 21 2015, by Noam N. Levey, Chad Terhune And David Willman, Tribune Washington Bureau

A commonly used medical scope linked to a deadly bacterial outbreak at UCLA's Ronald Reagan Medical Center may be so flawed it cannot be properly cleaned, federal officials conceded Thursday. But they stopped short of recalling the device or outlining any new sterilization procedures.

The U.S. Food and Drug Administration has known about the potential problems for more than two years, and took action only after the Los Angeles Times reported this week that two patients died in a new superbug outbreak at the UCLA facility. At least five other patients have tested positive for the drug-resistant bacteria, and 179 others may have been exposed.

Critics immediately complained about the FDA's failure to act.

"FDA didn't do its job," said Diana Zuckerman, president of the nonprofit National Center for Health Research.

Zuckerman questioned why the agency approved the device if it can't be effectively cleaned. She and other experts urged the FDA to issue clearer guidance to hospitals and other medical providers.

An FDA spokeswoman said that the devices' benefits outweighed the risks.

"If we pulled the devices from the market, we would prevent hundreds of thousands of patients from accessing a beneficial and life-saving procedure," said the spokeswoman, who, like other agency officials, spoke on condition she not be named. "So at this time, the continued availability of these devices is in the best interest of the public health."

The devices, called duodenoscopes, which feature a tiny camera mounted on the end of a tube that is threaded down a patient's throat and into the digestive tract, are commonly used by physicians to diagnose and treat cancer, gallstones and other conditions. Nationally, about half a million patients each year undergo the procedure, called ERCP, or endoscopic retrograde cholangiopancreatography.

Duodenoscopes are considered much less invasive and risky than surgery. And doctors credit them with saving lives through early detection and treatment.

The infections at UCLA are the latest in a series of outbreaks linked to duodenoscopes in recent years that have sickened patients at hospitals in Pennsylvania, Illinois and Seattle.

The FDA said Thursday that from January 2013 to December 2014, it received reports of 135 patients potentially infected by contaminated scopes.

But medical experts and safety advocates have been reporting potential design flaws for years.

In October, a study in the *Journal of the American Medical Association* linked bacterial infections to duodenoscopes at an Illinois hospital, even though researchers found no cleaning lapses.

The FDA acknowledged this problem in its new warning: "Some parts of

the scopes may be extremely difficult to access, and effective cleaning ... may not be possible."

The agency noted that moving parts in the scopes contain microscopic crevices that can't be reached with a cleaning brush and may harbor residual body fluids and organic debris that could expose subsequent patients to serious infections.

One type of bacteria, known as CRE, are particularly dangerous because they can't be treated with most antibiotics, leading to mortality rates of up to 50 percent, according to the Centers for Disease Control and Prevention.

Unless regulators give hospitals and physicians better guidance or the scopes are redesigned, more patients will get sick, said hospital safety consultant Lawrence Muscarella.

"There are no corrective actions that tell me how to address the problem," he said.

Sen. Patty Murray, D-Wash., who urged the FDA to update its safety guidance after a Seattle hospital reported that 11 patients died in a similar bacterial outbreak, also said more should be done to ensure patients' safety. Murray is the senior Democrat on the Senate Health Committee.

FDA regulators urged medical providers Thursday to carefully follow manufacturers' cleaning instructions and talk to patients about the benefits and risks of undergoing procedures that involved duodenoscopes.

"The FDA's move is a step in the right direction, but it doesn't have a lot of guidance about how to reduce the risk beyond what was already

known," said Dr. Jeffrey Duchin, an epidemiologist who oversaw the Seattle-King County investigation of the recently disclosed bacteria outbreak at Virginia Mason Medical Center in Seattle.

"Many clinicians and people I work with in the public health community are frustrated by the pace at which the issued is being addressed," he said.

Nancy Foster, vice president for quality and patient safety at the American Hospital Association, called the FDA's guidance "problematic."

"We want to be able to rely on the guidance to get the result that we want, and what we want is a clean endoscope," she said.

Olympus, the market leader in duodenoscopes, said in a statement Thursday that it was making available to its customers supplemental educational materials, including an interactive checklist with video demonstrations. "We are working with the FDA, relevant medical societies and our customers regarding these concerns," the company reported.

FDA officials were reluctant Thursday to discuss what other steps they may take, but the spokeswoman said the agency was trying to determine what it could do to limit infections.

UCLA has said it changed its decontamination procedures after discovering CRE in a patient in late January. It also alerted county and state health authorities at that time. No new cases have been found since UCLA began using gas sterilization. The gas, which is highly toxic, carries its own risks, however.

Many medical centers are looking for alternatives.

Some hospitals now quarantine their endoscopes for 48 hours after cleaning to check for bacterial growth. That system has drawbacks for busy hospitals because the scopes are unavailable for an extended period.