

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

February 23, 2015

The Honorable Jason Chaffetz
Chairman
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Elijah Cummings
Ranking Member
Committee on Oversight and Government Reform
2471 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Chaffetz and Ranking Member Cummings:

I write to request an Oversight and Government Reform Committee hearing and investigation into multiple sterilization failures of a medical device known as the duodenoscope. The sterilization problems have led to multiple deaths nationwide and repeated outbreaks of antibiotic-resistant bacteria. The Food and Drug Administration (FDA) issued a safety alert after the recent publication of a Los Angeles Times investigation. Because this issue poses both health and national security risks, an appropriate first step may be to hold a joint hearing of the Health Care, Benefits and Administrative Rule and National Security Subcommittees of the Committee on Oversight and Government Reform.

Recently in my district, at the UCLA Ronald Reagan Medical Center, 179 patients were potentially exposed to a deadly bacterial outbreak of Carbapenem-Resistant Enterobacteriaceae (CRE), also known as a "superbug." So far seven patients have been infected and two killed by CRE (*Los Angeles Times*, February 18, 2015, "Superbug linked to 2 deaths at UCLA hospital; 179 potentially exposed"). The deadly superbug outbreak is linked to duodenoscopes that were not thoroughly sterilized. CRE, especially in a hospital setting, is contagious.

Duodenoscope-linked outbreaks have occurred multiple times in our nation over the last few years, including in Pennsylvania, Illinois and Washington State. At Virginia Mason Medical Center in Seattle, 35 patients fell ill and 11 died from duodenoscopes that were not completely sterilized between 2012 and 2014 (*CBS News*, January 22, 2015, "Deadly superbug infected patients at Seattle hospital"). From 2013 to 2014, the FDA received reports of tainted duodenoscope problems on 135 patients.

The design of the duodenoscopes makes them very difficult to thoroughly clean (*Los Angeles Times*, February 19, 2015, "FDA knew of design flaw in scope linked to UCLA superbug"). According to the *Times* investigation, the FDA knew about the design and sterilization problems of duodenoscopes for over two years. Manufacturers of the device apparently knew about the design challenges as well. In the case of UCLA, it appears the design of the device allowed the CRE bacteria to spread despite UCLA following the manufacturer's recommended cleaning protocols.

CRE outbreaks have national security ramifications. President Obama issued an executive order on September 18, 2014 stating that "combating antibiotic-resistant bacteria is a national security priority." The President directed federal agencies "to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria." In 2013, the Centers for Disease Control and Prevention (CDC) issued a report, "Antibiotic resistant threats in the United States," that called CRE an "urgent threat."

While federal agencies such as the CDC are combating superbugs, the current recommended sterilization procedures would continue to result in superbug outbreaks and deaths. The FDA's recent safety alert, dated February 19, 2015, states that following the manufacturers' recommended cleaning protocols "may not entirely eliminate" the risk of transmitting infection. Hospitals that have experienced duodenoscope-linked superbug outbreaks, however, are using alternative methods of sterilization that may be more effective.

The duodenoscope is an important device that has saved countless lives and should continue to be used. But the current design of the device and current FDA-approved sterilization procedures have resulted in, and will continue to result in, CRE outbreaks and deaths.

If unmitigated, the human and societal costs of CRE outbreaks will continue to rise. A superbug infection can kill not only the patient who was exposed to a tainted duodenoscope, but also family members, friends, and hospital staff who interacted with the patient. Once an outbreak happens, the entire hospital may be at risk. Since CRE is very difficult to remove, hospitals need to devote significant resources to address a CRE outbreak. In 2011 for example, the National Institutes of Health Clinical Center built a wall to isolate patients, gassed rooms with vaporized disinfectant and ripped out plumbing in an attempt to stop the spread of a deadly outbreak of antibiotic-resistant bacteria (*Washington Post*, February 19, 2015, "FDA warns about medical scopes after 'superbug' hits California hospital").

Understanding and addressing the problems posed by duodenoscopy-linked superbug outbreaks is one step forward in combating the health and national security threats posed by antibiotic-resistant bacteria. The Committee's involvement in this issue would be consistent with its oversight plan, which states the Committee will conduct oversight of the FDA "with a focus on ensuring that FDA strikes the right balance between the availability of drugs and medical devices and patient safety." Because of the gravity of the superbug issue, the Committee may also want to consider broadening the topic to antibiotic-resistant bacteria outbreaks in general.

As a Member of the Committee on Oversight and Government Reform, I respectfully request a full committee hearing, or a joint Health and National Security Subcommittee hearing, to investigate these life and death issues.

Sincerely,



Ted W. Lieu
Member of Congress

cc:

Representative Jim Jordan, Chairman, Health Subcommittee
Representative Matt Cartwright, Ranking Member, Health Subcommittee
Representative Ron DeSantis, Chairman, National Security Subcommittee
Representative Stephen Lynch, Ranking Member, National Security Subcommittee