TED LIEU
33RD DISTRICT, CALIFORNIA

415 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3976

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

March 4, 2015

The Honorable Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

There have been a disturbing number of fatal outbreaks of antibiotic resistant bacteria. Many of these outbreaks have been linked to the use of contaminated duodenoscopes. An outbreak occurred at the UCLA Ronald Reagan Medical Center last week, following a string of other recent outbreaks across the country, including cases in Illinois, Washington State, and Pennsylvania. We share the Food and Drug Administration's (FDA) interest to effectively prevent the spread of infection, and we respectfully request the Agency's assistance in taking any and all steps that will help society reach that goal. As Members of Congress concerned about these deadly outbreaks, we write to both seek answers from the FDA regarding current and future sanitization protocols, and to create a partnership that works towards finding comprehensive solutions to keep Americans safe from the threat of superbugs.

As you know, Carbapenem-Resistant Enterobacteriaceae (CRE) is a highly contagious family of pathogens that not only spread easily in a hospital setting and can kill around 50 percent of patients infected[1], but also cannot be stopped by any known antibiotic, effectively making it a "superbug." At UCLA hospital, seven patients have been infected and two killed by CRE.[2] At Advocate Lutheran General Hospital in Illinois, 44 patients cultured positive for CRE by December 2013, of whom 38 had received an endoscopic procedure between January and September 2013[3]. At Virginia Mason Medical Center in Seattle, 35 patients fell ill, and 11 died from tainted duodenoscopes that were not completely sterilized between 2012 and 2014.[4] A Philadelphia hospital also experienced a CRE outbreak in 2014 where eight patients became infected and two died, though the officials from city's Department of Public Health have stated the deaths were not directly related to the infection, and have also refused to name the hospital for fear of causing "adverse publicity to discourage reporting of future cases".[5]

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[1] *Time,* February 23, 2015, "2 Superbug Deaths Reported in North Carolina."
[2] *Los Angeles Times*, February 18, 2015, "Superbug linked to 2 deaths at UCLA hospital; 179 potentially exposed."
[3] *Chicago Tribune*, January 10, 2014, "Superbug found at suburban hospital."
[4] *CBS News*, January 22, 2015, "Deadly superbug infected patients at Seattle hospital."
[5] *Philly.com,* February 21, 2015, "Superbug found in Phila. now in L.A.; FDA acts."

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While we recognize that duodenoscopes are not a leading cause in the spread of CRE, the continual occurrence of outbreaks must be taken very seriously. No matter how it is spread, it is clear that the threat posed by antibiotic-resistant bacteria is so serious that President Obama issued an Executive Order last September declaring that combating superbugs 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."

A superbug infection can sicken or kill not only the patient exposed to a tainted duodenoscope, but also family members, friends, and hospital staff who interacted with the patient. Once an outbreak occurs, 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.[6]

It appears that the FDA has known for at least two years that the design of duodenoscopes could result in CRE outbreaks.[7] CNN reports that the FDA may have known about the cleaning issues as early as 1987.[8] From 2013 to 2014, the FDA received 75 reports of sterilization problems with duodenoscopes, affecting 135 patients. In the February 19, 2015 FDA safety alert issued after the publication of the *Los Angeles Times* investigation, the FDA stated that following the recommended cleaning protocols could still result in failure to remove CRE from the medical scope. The safety alert does not appear to have changed the status quo, allowing CRE outbreaks caused by tainted duodenoscopes to continue to occur.

Some hospitals, however, have begun using other means to ensure duodenoscopes are completely sterile before using them, such as testing the devices for post-sterilization contamination, instituting a waiting period, or using alternative cleaning methods. Virginia Mason Medical Center purchased additional duodenoscopes, hired more staff, and quarantined the devices for forty-eight hours before reuse.[9] Both UCLA and Advocate Lutheran General switched to gas cleaning. Many hospitals, however, may lack the resources to implement similar measures, and gas cleaning may put others at risk if residual amounts of the toxic gases remain on the scopes. It appears that if a superior cleaning procedure cannot be developed, the best solution will be to develop a new device.

We recognize that duodenoscopes are essential to the medical field and are used on an estimated 500,000 patients each year. We understand the important diagnostic and preventative role this device serves, and the countless lives it has saved. We want to work with the FDA to find a long-term solution to limit the number of duodenoscope-linked superbug outbreaks. In that spirit, we request answers to the following questions:

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[6] *Washington Post*, February 19, 2015, "FDA warns about medical scopes after 'superbug' hits California hospital."
[7] *Los Angeles Times*, February 19, 2015, "FDA knew of design flaw in scope linked to UCLA superbug."
[8] CNN, February 25, 2015 "Scope superbug: How long did the FDA know about problem?"
[9] *Los Angeles Times*, February 20, 2015 "Hospitals grapple with safety of scopes after UCLA outbreak."

1. When did the FDA first learn that the design of duodenoscopes made them difficult to sterilize and could lead to infection? What communication between the FDA and duodenoscope manufacturers took place subsequent to acquisition of that knowledge?

2. What steps is the FDA taking to encourage manufacturers of current duodenoscopes to come up with a design that would limit CRE infections? What steps is the FDA taking to ensure that existing medical devices are cleaned correctly? If new medical devices that replace duodenoscopes are found to be necessary, to what sanitization standards will those devices be held?

3. Prior to the February 19, 2015 safety alert, what steps did the Agency take to warn hospitals, doctors and patients about the risks of CRE infection from duodenoscope procedures?

4. One of the major manufacturers of duodenoscopes recommends gas cleaning as an alternative. Does the Agency agree?

5. Does the FDA recommend instating a 48-hour waiting period and subsequent bacterial growth test of duodenoscopes prior to reuse?

6. What factors does the FDA recognize as contributing to increased occurrences of superbug outbreaks? What steps are being taken by the FDA to mitigate outbreaks, and what remedial steps does the Agency believe other involved entities should take?

7. Knowing patients are faced with few or no treatment options when diagnosed with a deadly superbug, what steps is the FDA taking to help ensure safe, novel antimicrobials for superbugs are getting through the development pipeline? What more does the Agency believe it can be doing to facilitate that end?

8. In the FDA's cost-benefit analysis of allowing the current status quo to continue, did the FDA consider the threat that CRE poses not just to the patient, but also the patient's family, hospital staff, and the entire hospital? Did the FDA consider the costs to the hospital to eliminate a CRE outbreak?

9. Given President Obama's Executive Order declaring that combating superbugs is a "national security priority," has the FDA's Office of Counterterrorism and Emerging Threats considered developing medical countermeasures to address the challenge of duodenoscope-acquired infections?

10. To what extent has the FDA coordinated with our country's national security apparatus on preventing superbug outbreaks?

11. What standards currently does FDA require for the cleaning of duodenoscopes? What happens if a duodenoscope fails to be cleaned to those standards?

Thank you in advance for answering our questions. Superbugs are a critical national security and public health threat, yet hundreds of thousands of patients across the nation rely on duodenoscopes. We must find a way to address this challenge, update the cleaning protocols or redesign the device, and ensure hospitals, doctors, and patients have the necessary information regarding duodenoscopes. This is not an easy problem to resolve, and we look forward to working together with the FDA to find a permanent solution to this critical public health risk.

Sincerely,

Ted W. Lieu
Member of Congress

Peter J. Roskam
Member of Congress

Danny K. Davis
Member of Congress

Vernon G. Buchanan
Member of Congress

Rosa L. DeLauro
Member of Congress

Earl Blumenauer
Member of Congress

Alcee L. Hastings
Member of Congress

Ted S. Yoho
Member of Congress

Michael G. Fitzpatrick
Member of Congress

Michael F. Doyle
Member of Congress

Dan Newhouse
Member of Congress