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 27, 2015

David Woods
President
PENTAX Medical a Division of PENTAX of America, Inc.
3 Paragon Drive Montvale,
New Jersey, 07645-1782

Dear Mr. Woods:

Thank you to PENTAX Medical for making medical devices that have improved the quality of life for patients. The PENTAX duodenoscope, however, has been linked to repeated outbreaks and possible deaths of antibiotic-resistant bacteria nationwide, including an outbreak at Lutheran General Hospital in Illinois. Reports indicate that even when hospitals follow PENTAX's cleaning instructions, Carbapenem-Resistant Enterobacteriaceae (CRE) can still remain on the duodenoscope.[1] Another leader in duodenoscope manufacturing, Olympus, whose tainted device caused an outbreak of CRE in my district, has now updated its cleaning protocols in close consultation with the Food and Drug Administration (FDA).

CRE outbreaks caused by duodenoscopes also 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."

I am writing to get answers from PENTAX that will help inform policymakers in formulating responses to this health and national security problem, and I would like reassurance that PENTAX is urgently addressing the current situation. Further, I would like to know PENTAX'S reaction to Olympus's new cleaning procedures, and whether PENTAX is following a similar approach to Olympus. I am also writing to inquire whether PENTAX can help hospitals cope with a scope design that has led to deadly CRE outbreaks.

I request that PENTAX answer the following questions:

1. What plans, if any, is PENTAX pursuing to redesign its duodenoscope so that the scope can be cleaned reliably?

[1] *FDA to require proof that resusable medical devices can be reliably cleaned*, Washington Post, March 12, 2015

2. What plans, if any, does PENTAX have to recall the current duodenoscope and replace it with one that can be cleaned reliably?

3. When did PENTAX first learn that its duodenoscope was causing CRE infections and outbreaks? What did PENTAX do with that information?

4. What alternative cleaning methods, if any, does PENTAX recommend that hospitals use to clean the current PENTAX duodenoscope?

5. Does PENTAX believe all hospitals using the PENTAX duodenoscope should follow the duodenoscope surveillance protocol recently published by the CDC?[2]

6. What information does PENTAX believe should be provided to patients who undergo procedures that require the PENTAX duodenoscope?

7. Olympus America, another leader in duodenoscope manufacturing, has updated their cleaning guidelines. What is PENTAX's opinion of these guidelines, and will you follow Olympus's lead and release similar cleaning guidelines?

The design and cleaning problems with the PENTAX duodenoscope has caused CDC to issue new duodenoscope surveillance protocols to guard against CRE contamination. Many hospitals nationwide and in my district now follow these protocols, or resort to alternative cleaning methods such as gas cleaning, to address the apparent design defect in the PENTAX duodenoscope. These new protocols, however, render the duodenoscope inaccessible for 24 hours, 48 hours, or more. This has now caused hospitals that have experienced CRE outbreaks from PENTAX duodenoscopes to purchase even more PENTAX duodenoscopes.

Hospitals initially purchased PENTAX duodenoscopes with the understanding that the scopes can be used multiple times during the day and that they can be reliably cleaned. Neither assumption seems true. PENTAX thus sold a product that failed to perform to its specifications.

It seems fundamentally unfair for PENTAX to be selling more duodenoscopes to these same hospitals as a result of the design problems created by PENTAX in the first place. Endoscopy expert Lawrence Muscarella recently stated, "In an ironic twist, the CDC protocol would likely increase sales of the devices."[3] I would like to ask whether PENTAX—as a show of good faith that the company is trying to remedy the situation—would consider donating additional duodenoscopes to hospitals that resort to alternative cleaning methods, or providing the scopes at cost without a profit, until the design or cleaning problems have been resolved.

Thank you for your attention to this serious matter. Multiple patients nationwide have been exposed to the deadly CRE infection as a result of from PENTAX duodenoscopes. Hospitals are now spending increasing amounts of money to prevent CRE outbreaks arising from

---

[2] *CDC issues interim duodenoscope surveillance protocol*, Infection Control Today, March 12, 2015

[3] *Exclusive: U.S. health officials push for stricter 'superbug' defense*, Reuters, February 20, 2015

an apparent design defect in the PENTAX product. The antibiotic-resistant bacteria outbreaks associated with PENTAX duodenoscopes also impact one of America's national security priorities. I look forward to working with PENTAX and other stakeholders to resolve the current problems as soon as possible. I am also happy to meet regarding these critical issues.

Sincerely,

Ted W. Lieu
Member of Congress

cc:
Food and Drug Administration
Centers for Disease Control and Prevention