United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

May 9, 2019

David Woods
President and Chief Executive Officer
Pentax Medical
3 Paragon Drive
Montvale, New Jersey 07645

Dear Mr. Woods:

Last month, the Food and Drug Administration (FDA) released new data revealing alarmingly high rates of contamination in certain duodenoscopes, even after the device is cleaned. These data raise serious questions about your company's ability to ensure the health and safety of patients who undergo procedures using Pentax-manufactured closed-channel duodenoscopes. I am writing today to understand how your company plans to respond to these troubling findings and what changes may be necessary going forward to ensure patient safety. While important steps have been taken to reduce outbreaks, it is unacceptable that one in twenty patients who undergo a procedure using a duodenoscope may acquire an infection as a result of that procedure – even when hospitals have followed cleaning instructions correctly.

In October 2015, FDA ordered your company to conduct postmarket surveillance studies to understand how closed-channel duodenoscopes are reprocessed in real-world settings and evaluate the effectiveness of cleaning techniques on duodenoscope contamination.[1] In March 2018, FDA issued a warning letter to Pentax for failure to conduct the postmarket surveillance studies; Pentax responded to the warning letter with plans to meet FDA's study milestones. In December 2018, FDA released interim findings from the sample studies.[2] These studies revealed 3 percent of samples tested positive for high concern organisms (including antibiotic-resistant bacteria), and 3 percent tested positive for low concern organisms (those unlikely to cause disease but still indicative of cleaning failure). On April 12, 2019, FDA released an update from the sampling studies showing the rate of contamination is even higher: 5.4 percent of all properly collected samples tested positive for high concern organisms, and up to 3.6 percent of properly collected samples tested positive for low to moderate concern organisms.[3] These rates far exceed the contamination rate FDA hoped to see: less than 1 percent or as close to zero as possible for duodenoscopes.

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[1] https://www.fda.gov/medical-devices/safety-communications/fda-continues-remind-facilities-importance-following-duodenoscope-reprocessing-instructions-fda

[2] https://www.fda.gov/news-events/press-announcements/statement-jeff-shuren-md-jd-director-center-devices-and-radiological-health-updated-safety

[3] https://www.fda.gov/news-events/press-announcements/statement-jeff-shuren-md-director-center-devices-and-radiological-health-continued-efforts-assess

Since 2015, I have been conducting oversight of duodenoscopes, and in 2016, I issued a report highlighting serious problems with the ability of regulators and manufacturers to identify and respond to patient safety issues.[4] I remain concerned about the risk of infection posed by these devices and committed to ensuring rigorous oversight of the safety of Pentax medical devices. To that end, I request that you provide the following information no later than May 23, 2019:

1. A copy of each Medical Device Report (MDR) that Pentax has submitted to the FDA related to contamination of a closed-channel duodenoscope between January 2017 and today.

2. The rate of contamination for both high concern organisms and low to moderate concern organisms identified in interim results from the FDA-ordered sampling studies.

3. When does Pentax project it will complete both FDA-ordered postmarket surveillance studies?

4. Has Pentax conducted any analysis of these interim findings? If so, please provide that analysis.

5. How does Pentax plan to address the findings of its postmarket surveillance studies? What is Pentax's position on whether closed-channel duodenoscopes remain safe for patient use?

6. What feedback has Pentax received from users of the Pentax closed-channel duodenoscopes concerning the cleaning and reprocessing instructions or any issues related to device maintenance?

7. Has Pentax engaged in any effort to re-design or modify the closed-channel duodenoscope in order to address concerns about the ability of the device to be properly cleaned?

Thank you in advance for your attention to this matter. If you have any questions, or would like to further discuss compliance with this request, please contact Carly Rush or Elizabeth Letter with Senator Murray's HELP Committee Staff at 202-224-0767.

Sincerely,

Patty Murray
United States Senator
Ranking Member, Senate Committee on
Health, Education, Labor, and Pensions

[4] https://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf

cc: Lamar Alexander
United States Senator
Chairman, Senate Committee on
Health, Education, Labor, and Pensions