Summary of Proposed Legislative Provisions

The evidence obtained by the Committee on Oversight and Government Reform during its investigation of duodenoscope-related patient infections identified significant gaps in existing law that contributed to preventable bacterial outbreaks. In addition to the provisions contained in S. 2503, three provisions are needed to ensure that FDA and healthcare providers are equipped to prevent unnecessary bacterial infections by reusable medical devices. These provisions would:

(1) require manufacturers to notify FDA when they change their designs or reprocessing instructions, regardless of whether their devices are required to be resubmitted for regulatory approval;

(2) require manufacturers to inform FDA when they alert their foreign customers of problems with the design and cleaning of their devices; and

(3) require FDA to regulate rapid assessment tests as medical devices.

I. REPORTING REQUIREMENT FOR DESIGN CHANGES

The evidence obtained by the Committee demonstrates that manufacturers of duodenoscopes failed to report significant changes they made to the design of their devices. As a result, FDA did not evaluate those changes for years after they were introduced into the market.

For example, in 2010 Olympus introduced a major change to its duodenoscope design that closed the elevator channel, making it impossible to clean behind an O-ring seal. The company did not report the change to FDA, and the new model was not evaluated for safety for years.

In November 2010, Olympus made a cursory reference to its new model, the 180V, in a mandatory filing known as a Medical Device Report (MDR) following an adverse event.[1]

FDA responded by asking Olympus for details about its new model and to "list any modifications or enhancements which have been implemented (or are planned)" compared to the previous model.[2]

Olympus responded with a long list of modifications it had made, including:

- "Add directions, warnings, and information about the guidewire locking function (especially about the side lock) to the operation manual.
- Add ancillary devices that can be used with the endoscope to the operation manual.

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[1] Letter from Laura Storms-Tyler, Vice President of Regulatory Affairs and Quality Assurance, Olympus America, Inc., to Deborah Yehia, Center for Devices and Radiological Health, Food and Drug Administration (Feb. 4, 2011).

[2] *Id*.

- Change the maximum diameter of the insertion tube to 15.0 mm.

- Change the material of the L arm; this is a metal piece that is connected to the forceps raiser, and with part# GE678500."[3]

However, the company omitted reporting the design change to seal the elevator-wire channel. This omission was significant. In March 2014, FDA requested that Olympus submit the 180V for regulatory approval, stating that "we believe that sealing the elevator channel, and consequently, preventing sterilization and high level disinfection of the elevator channel, impacts the safe use of the device."[4]

Under federal law, medical device manufacturers are required to report modifications that could significantly affect the safety or effectiveness of the device.[5] However, if a manufacturer believes a modification is minor, it may proceed to market without requesting FDA approval.[6]

New legislation is needed to improve FDA awareness of device design or reprocessing changes by requiring that all changes be reported to FDA. The provision would read as follows:

> REPORTING REQUIREMENT FOR DEVICE DESIGN AND REPROCESSING INSTRUCTION CHANGES.—Before making a change to the design of a device, or the reprocessing instructions of a device, that is marketed in interstate commerce, the manufacturer of the device shall give written notice of the change to the Food and Drug Administration.

II. REPORTING REQUIREMENT FOR COMMUNICATIONS TO FOREIGN HEALTH CARE PROVIDERS

The evidence obtained by the Committee demonstrates that Olympus issued safety warnings and introduced safety enhancements in Europe for its closed-elevator channel duodenoscopes considerably earlier than it did in the United States and did not inform FDA officials about them.

Olympus issued safety warnings in January 2013 instructing European health providers to use a special brush provided by Olympus to clean their 180V closed-elevator channel

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[3] *Id*.

[4] Letter from LaShanda Long, Chief, Center for Devices and Radiological Health, Food and Drug Administration, to Laura Storms-Tyler, Vice President, Olympus Medical Systems Corporation (Mar. 18, 2014) (online at www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM436587.pdf).

[5] Memorandum from Congressional Research Service to House Committee on Oversight and Government Reform Staff (Nov. 23, 2015).

[6] *Id*.

duodenoscopes. Olympus distributed these safety notifications in Netherlands and Switzerland, among other places.[7]

Olympus' instructions directed providers: "Use one of the recommended brushes to brush the front and rear side of the forceps elevator."[8] Olympus recommended: "The MAJ-1888 brush can be used for heavy soiling or delayed reprocessing situations and enables deeper access to the forceps elevator."[9]

In July and August 2014, Olympus contacted European customers again, issuing a safety communication entitled, "URGENT: Field Safety Corrective Action" announcing updated cleaning manuals for the company's TJF-Q180V model:

> As a result of our complaint investigations, Olympus has determined to revise our reprocessing instructions and recommends the use of an additional cleaning brush. The additional brush is the MAJ-1888. Olympus recommends brushing around the forceps elevator with the MAJ-1888 brush in addition to the existing MH-507 brush in order to adequately clean around the forceps elevator more thoroughly.[10]

Olympus sent these safety notifications in Europe before the majority of major outbreaks in the United States occurred. Olympus did not inform FDA about these safety notices and did not issue similar safety warnings in the United States at the time.[11]

It was not until February 19, 2015, that Olympus distributed its first public safety communication to U.S. healthcare providers, more than two years after the similar communications in Europe.[12] This communication, however, made no mention of the existence of the MAJ-1888 brush, which the company was recommending in Europe.

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[7] Swiss Agency for Therapeutic Products, *Medical Devices—List of Recalls and Other Field Safety Corrective Actions* (Jan. 2013) (accessed on Dec. 25, 2015) (online at www.swissmedic.ch); Dr. Margreet Vos, *The Role of the ERCP Duodenoscope in the Outbreak by VIM Positive P. Aeruginosa at the Erasmus MC* (May 14, 2015) (www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM446944.pdf).

[8] Olympus Europa Holding Gmbh, *Important Safety Advice Safe Reprocessing of TJF-Q180V* (Jan. 2013) (online at www.swissmedic.ch/recalllists_dl/07207/Vk_20130123_15-e1.pdf).

[9] *Id*.

[10] Olympus, *URGENT: Field Safety Corrective Action* (Aug. 2014) (online at www.swissmedic.ch/recalllists_dl/10220/Vk_20140729_02-e1.pdf).

[11] Briefing by the Food and Drug Administration to House Committee on Oversight and Government Reform Staff (Jan. 8, 2016).

[12] Olympus America Inc., *URGENT: IMPORTANT SAFETY INFORMATION* (Feb. 19, 2015) (online at medical.olympusamerica.com/sites/default/files/pdf/TJF-Q180V_Customer_FINAL_English.pdf).

On March 26, 2015, Olympus finally announced the introduction of the MAJ-1888 brush in the United States:

> The revised cleaning procedure requires brushing of the forceps elevator recess with two different-sized brushes. In addition to that brush that is currently used to clean the elevator recess area, the MAJ-1888 brush (or any Olympus MAJ-1888 equivalent) will be provided for further cleaning of this area. Olympus anticipates shipping the MAJ-1888 brushes no later than May 8, 2015.[13]

When Committee staff asked Olympus why its response in Europe had been so much faster than in the United States, company officials stated:

> In December 2012, in the context of ongoing discussions with regulators in the Netherlands regarding infections reported at Erasmus Medical Center, the Dutch Health Care Inspectorate asked Olympus to submit a field safety notice to Dutch customers to remind users of the importance of pre-cleaning and reprocessing. The regulators asked that the notice reference the recent case and indicate that reprocessing instructions must be closely observed, that endoscopes must undergo a through visual inspection (and be serviced if damaged), and that training is available. Olympus distributed the notice to European customers.[14]

New legislation is needed to require that communications like those sent by Olympus in 2013 and 2014 in Europe would have to be reported to the FDA. The provision would read as follows:

> REQUIREMENT.—The manufacturer of a device that is marketed in interstate commerce shall give written notice to the Food and Drug Administration of any communication described in paragraph (2) not more than 5 calendar days after making such communication...described in this paragraph if the communication—
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> (A) is made by the manufacturer of the reusable device or an affiliate of the manufacturer;
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> (B) relates to a change to the design of the device, a change to the recommended reprocessing protocols, if any, for the device, or a safety concern about the device; and

[13] Olympus America Inc., *Urgent Safety Notification Important Updated Labeling Information: New Reprocessing Instructions for the Olympus TJF-Q180V Duodenoscope* (Mar. 26, 2015) (online at medical.olympusamerica.com/sites/default/files/pdf/150326_TJF-Q180V_Customer_letter.pdf).

[14] Letter from Robert K. Kelner, Covington and Burling LLP, on behalf of Olympus Corporation of the Americas, to House Committee on Oversight and Government Reform Staff (July 2, 2015).

(C) is widely disseminated (including on a voluntary basis) to health care providers in a foreign country.

III. REGULATION OF RAPID ASSESSMENT TESTS AS MEDICAL DEVICES

Rapid assessment tests of bacterial contamination can detect ATP, a molecule that micro-organisms use for energy, as well as carbohydrates and proteins that are indicators that bacteria may be present.

Current law does not regulate rapid assessment tests as medical devices, and experts warn that they have not been subjected to rigorous evaluation. The American Society of Microbiology stated that these rapid tests "have not been well validated" to show that they can detect living bacteria.[15] Dr. Michelle Alfa, a nationally known expert, has stated:

> [T]here is no currently available rapid test that has been properly validated that can be used post-HLD on duodenoscopes to show that there are no viable bacteria and that the endoscope is safe to use on the next patient.[16]

Regulating these tests would ensure that they are effective and work as their manufacturers claim. As Dr. Alfa explained:

> Regulation could ensure there is validation of the label-claims thereby ensuring the rapid test is appropriate for either cleaning testing or post-HLD testing for viable bacterial residuals. Currently, it is left up to the manufacturer as to what validation is performed and it is often unclear to healthcare providers exactly what the test method can be used for (i.e. cleaning adequacy versus post-HLD levels of viable microorganisms).[17]

New legislation is needed to require the FDA to regulate rapid assessment tests as medical devices. The provision would read as follows:

> (a) INCLUSION IN DEVICE DEFINITION.—Section 201of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—(1) in paragraph (h)—…(C) by inserting after subparagraph (3) the following:
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> ''(4) a rapid assessment test intended to ensure the proper reprocessing of a reusable device (as defined in paragraph (ss)), and."

[15] Email from Dr. Kimberly Walker, Public Affairs Manager, American Society of Microbiology, to House Committee on Oversight and Government Reform Staff (Jan. 15, 2016).

[16] Letter from Dr. Michelle Alfa, Professor of Medical Microbiology, University of Manitoba, to House Committee on Oversight and Government Reform Staff (Jan. 19, 2016).

[17] *Id.*