

Preventing Superbugs and Protecting Patients Act

Between 2013 and 2015, over 250 patients worldwide suffered serious infections after undergoing a medical procedure using a type of reusable medical device, known as a duodenoscope. Some of these infections involved multi-drug resistant organisms often called “superbugs.” In early 2015, after these events began coming to light, Senator Murray, Ranking Member of the Senate Health, Education, Labor, and Pensions Committee, initiated an investigation to determine the events that led to these outbreaks and help protect patients and families from future tragedies.

The year-long investigation revealed that the outbreaks were more widespread than previously reported, and that improvements on the part of multiple stakeholders – including manufacturers, FDA and its regulatory system, and hospitals – could have prevented the outbreaks. Senator Murray’s final report summarizing the investigation made several recommendations that would help address issues the investigation uncovered. The Preventing Superbugs and Protecting Patients Act advances two of the recommendations made in the report:

- **Requiring manufacturers of reusable medical devices like duodenoscopes to submit proposed cleaning instructions and validation data to FDA before marketing the devices.** The bill amends the Federal Food, Drug, and Cosmetic Act to require that a manufacturer of a reusable medical device, like a duodenoscope, submit proposed labeling and validated reprocessing data as part of a pre-market 510(k) submission to the FDA. The bill provides the FDA with explicit statutory authority to refuse or deny the submission and marketing clearance if a manufacturer fails to provide this information.
- **Making clear to device manufacturers when they must seek and obtain FDA clearance before marketing modified devices.** The legislation requires FDA to expeditiously finalize its guidance about when manufacturers are required to seek FDA clearance before marking modified devices.

To view the full report, please visit:

<http://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf>