ConsumersUnion

POLICY & ACTION FROM CONSUMER REPORTS

The Honorable Senator Patty Murray
United States Senate
154 Russell Senate Office Building
Washington, D.C. 20510

February 8, 2016

Dear Senator Murray,

On behalf of Consumers Union, the public policy and advocacy arm of Consumer Reports, we are writing to express our strong support for the Preventing Superbugs and Protecting Patients Act. As patient safety consumer advocates who have worked extensively on medical device safety problems, we believe that this bill, which implements several recommendations from the excellent recently released HELP Committee minority report, "Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients, will improve patient safety by strengthening FDA oversight of medical devices.

This legislation is of utmost importance. Recent widespread infection control breaches – due to improper cleaning of duodenoscopes - put the American public in danger by spreading antibiotic resistant superbugs through these devices. At least 250 patients exposed to these scopes were infected with the deadly CRE bacteria, several died, and many more are colonized with superbugs, including CRE. These colonized patients are now more at risk for superbug infections and, when receiving health care in the future, present a greater potential for spreading the bacteria to other patients if health care workers do not adequately clean their hands or follow other infection control protocols.

The Preventing Superbugs and Protecting Patients Act takes important steps toward addressing the deficiencies of the current oversight of medical devices. It will strengthen oversight of reusable medical devices at the U.S. Food and Drug Administration (FDA) by requiring certain reusable medical devices being considered under section 510(k) to submit to FDA labeling materials regarding cleaning, disinfection and sterilization, including validation data. The FDA can use this information when determining substantial equivalence. The bill also requires the FDA to issue final guidance to make clear when a device company must submit premarket notice under Section 510(k) about modifications to devices already being marketed.

We welcome the introduction of the Preventing Superbugs and Protecting Patients Act and we thank you for your leadership on this issue. We urge your colleagues to prioritize patient safety and to support this bill.

Lisa McGiffert
Director, Safe Patient Project
lmcgiffert@consumer.org