ConsumersUnion

POLICY & ACTION FROM CONSUMER REPORTS

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

January 22, 2016

Dear Senator Murray,

On behalf of the Safe Patient Project at Consumers Union, we thank you for the recently-released HELP Committee report, "Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients." We commend you for the enormous amount of investigative work on the part of your office and the committee staff, for its scope and depth. As patient safety consumer advocates who have worked extensively on the problems presented by doudenoscope cleaning, we believe the attention you have brought to these issues will make a big difference in patients' lives.

The issues you raised around duodenoscopes highlight that, every step of the way, patients were left in the dark, and many lives were affected by the failure of systems that we have in place to keep patients safe. Your report appropriately emphasizes the need to make sure current requirements for accountability are followed and to implement new methods.

We are in agreement with the report's recommendations. We support a Congressional requirement to include unique device identifiers (UDIs) in insurance claims so that patients and healthcare providers can be contacted if problems with a specific device are identified. These UDIs also need to be included in electronic medical records. We believe that the status quo -- with no universal way to find out which devices went into which patients -- is utterly unacceptable and dangerous for patients.

We believe that accurate and timely reporting of adverse events by healthcare providers and device manufacturers is fundamental for improved patient safety. Hospitals must report errors in a more rigorous and expedient manner; thus we also support making Medicare funding contingent on hospitals' compliance with adverse event reporting.

We encourage you and the HELP Committee to keep in mind that consumers can make better healthcare choices when they are informed about these problems directly and in a timely manner. That is why we are calling on the President's Council to Combat Antibiotic Resistant Bacteria (CARB) to require hospitals, as a condition of participation in Medicare, to notify patients who have been exposed to superbugs through an outbreak or infection control breach. This includes patients going into hospitals during outbreaks, and, as in the case of contaminated scopes, patients exposed to devices that are the source of infections. The doctors of these patients should also be notified. Making sure this information gets to people when they really need it, and not years later, is imperative to addressing these safety concerns more quickly.

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We also urge the HELP Committee in particular to think carefully about these issues as it works through medical innovation legislation. The House medical innovation bill would weaken pre-marketing evaluation of drugs and devices, which we strongly oppose. The provisions in the 21st Century Cures bill not only speed up the approval process but also do not propose any mechanisms or FDA resources for improving post-marketing surveillance. As your report reveals, our current post-market monitoring is inadequate; pushing more evidence gathering into that system without first significantly improving and funding it is a recipe for disaster.

The essential goal of not harming patients can be achieved without distracting from true innovation; innovation and technological advancement only benefits consumers when there is a strong scientific basis for approval and a robust surveillance system. We understand the HELP Committee will begin to markup medical innovation bills in the coming weeks and we look forward to working with you to ensure that the Senate bills address the kinds of patient safety issues your report has raised.

Respectfully submitted,

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