Durbin & Schakowsky Introduce Legislation To Protect Patients, Improve The Medical Device Recall Process

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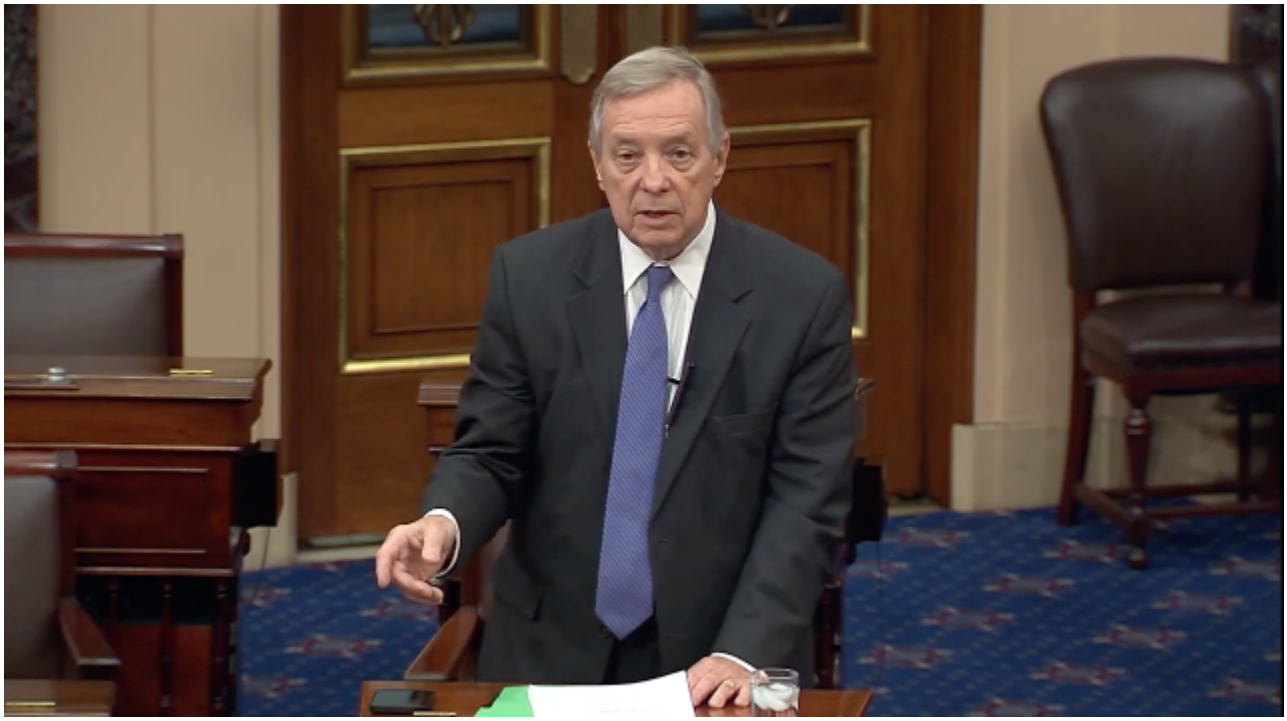

WASHINGTON – U.S. Senate Majority Whip Dick Durbin (D-IL) and U.S. Representative Jan Schakowsky (D-IL-09) today introduced bicameral legislation to improve the medical device recall process in order to protect patients. The *Medical Device Recall Improvement Act* would require the Food and Drug Administration (FDA) to establish an electronic format for medical device recall notifications to streamline communication between device manufacturers, FDA, hospitals, and health care professionals. It also would require manufacturers to include in recall notices information about how the recall could affect patients with medical devices and instruct hospitals and health care professionals to provide that information to patients. The

legislation was inspired by Illinois constituents who had shared their personal stories about medical harms and other concerns related to recalled devices.

FDA oversees the regulation of almost 200,000 medical devices in the U.S., from contact lenses and contraceptive devices to prosthetics and pacemakers. According to the American Medical Association, more than 32 million Americans have an implanted medical device, and countless others use them throughout their lives. These devices improve and save lives. However, medical devices that are recalled for safety issues or manufacturing defects can cause severe harm to patients.

Medical device manufacturers communicate recall information to FDA and health care professionals through letter and email. This extends the amount of time it takes FDA to review recall information, determine a recall classification, and communicate the recall to the public. It also extends the amount of time it takes hospital coordinators to track and pull recalled medical devices from inventories. As a result, patients are often the last informed about a recall—if ever. According to Consumer Reports, most Americans are not aware of recalls for their products, including medical devices.

“Millions of Americans rely on their medical devices to keep them healthy. When medical devices are recalled, patients have the right to know as soon as possible in order to understand the risks and consult with their health provider,” said Durbin. “The *Medical Device Recall Improvement Act* is an obvious solution to ensure that medical device manufacturers, FDA, and health providers can share up-to-date information as soon as possible.”

“Americans deserve to know that the medical devices they rely on for their health and wellbeing are safe,” said Schakowsky. “I am proud to partner with Senator Dick Durbin to introduce the *Medical Device Recall Improvement Act*, which will require all medical device recall information to be disseminated to the Food and Drug Administration in an electronic format, as opposed to physical mail, to reach health providers and patients quicker. Medical device companies initiate over 1,000 annual recalls, which impact millions of medical device units. Recalls save lives. We must ensure patients get this information in a timely manner, and our bill does just that.”

Specifically, the *Medical Device Recall Improvement Act* would:

- Require FDA to establish an electronic format for medical device recall notifications;
- Require medical device manufacturers to use the electronic format to contact FDA and hospitals and health providers; and

- Require medical device manufacturers to include information in recall notifications about the risks of the recalled device, and instruct hospitals and health providers to distribute the information to patients.

The *Medical Device Recall Improvement Act* has earned endorsements from Consumer Reports, Public Citizen, National Center for Health Research, Device Events, Breast Implant Safety Alliance, Medical Device Problems, Patient Safety Action Network, USA Patient Network, and UCSF Team for High-Value Care.