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Grassley, Kohl release report on FDA review of medical device safety

WASHINGTON – Senator Chuck Grassley of Iowa and Senator Herb Kohl of Wisconsin today released a report showing the need for the Food and Drug Administration (FDA) to enhance its assessment of recalls of medical devices to better mitigate the risk of serious health consequences from defective or unsafe devices.

"The gist of this report is that the FDA can't tell if recalls of high-risk devices were carried out successfully because it lacks criteria for assessing device recalls and doesn't routinely review recall data," Grassley said. "Recalls are typically voluntary, and patients would be better served if the FDA took a thorough approach to post-market surveillance of medical devices. Right now, it looks like the FDA is missing an opportunity to proactively identify and address risks presented by unsafe devices. Doing so would establish greater accountability for patients."

"Unfortunately, weaknesses in FDA's post-marketing surveillance of medical devices identified at a recent Committee on Aging hearing and again here by the GAO demonstrate the clear need to strengthen the post-market monitoring and recall process," Kohl said.

Grassley and Kohl requested this report of the Government Accountability Office (GAO). It's titled MEDICAL DEVICES: FDA Should Enhance Its Oversight of Recalls, GAO-11-468.

Grassley routinely conducts oversight of the Food and Drug Administration. Kohl recently conducted a hearing of the Special Committee on Aging, where he serves as Chairman, about the agency's approval process for medical devices.

The GAO said that, in 2007, medical devices were involved in 45 million inpatient procedures, 117 million hospital emergency room visits, 89 million hospital outpatient visits, and 994 million physician office visits. Medical devices range from tongue depressors to pacemakers and artificial heart valves.

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