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Senators Klobuchar, Franken and Representative Paulsen Address Institute of Medicine Report on 510(k) Review Process

*Minnesota leaders push to expedite process, cut red-tape to help spur innovation in
medical device industry*

Washington, D.C. – Today U.S. Senators Amy Klobuchar and Al Franken and U.S. Representative Erik Paulsen addressed a report released today by the Institute of Medicine (IOM) on the Food and Drug Administration's (FDA) 510(k) medical device approval process. All three members emphasized the need to maintain the 510(k) process, while making critical reforms needed to cut red tape and ensure the medical device industry has the consistency it needs to continue to drive innovation.

"Innovation and safety are vital to the success of the U.S. medical device industry," Klobuchar said. "Minnesota is a national leader in health care innovation and I believe we need targeted reforms to the 510(k) process to ensure that our companies in the medical device industry can continue to create jobs, develop innovative products, and maintain patient safety. Scrapping the 510(k) process entirely isn't what our businesses want and could limit access to life-saving products. I will continue to push for common-sense reforms that encourage innovation and patient safety and do not impose confusing and burdensome regulations on Minnesota businesses."

"Calling for the elimination of the 510(k) process could be very harmful to innovation," said Sen. Franken. "The report's recommendations would impose new burdens on the medical device industry, without a clear path to a more effective process. And in the meantime, it would leave Minnesota companies with great uncertainty, and patients without new lifesaving devices." "The 510(k) review process has long been regarded as a safe and effective way to bring much needed life saving products to the market. Eliminating it, as the IOM suggests, would be a step in the wrong direction," said Paulsen. "The medical technology industry is already facing unprecedented challenges - a job stifling innovation tax and an increasingly out-of-touch FDA - and eliminating the 510(k) process would give Europe another leg up in competing for these made-in-America technologies. What the medical devices manufactures need is consistency in the approval process, not more uncertainty. Instead of replacing 510(k), I intend to work with innovators, physicians, and other stakeholders to streamline the device clearance process at the FDA."

The report, titled "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years," was commissioned by the FDA to assess whether changes to the 510(k) program were needed and how best to improve the program to meet the complexity of today's medical device market.

The current 510(k) program has cleared safe and effective medical devices for decades, but needs targeted reforms to streamline the process for businesses. The Institute of Medicine concedes in its report that there is no public health crisis related to unsafe or ineffective medical devices.

Both the medical device industry and the Food and Drug Administration have acknowledged that improvements can be made to the 510(k) process and Klobuchar and Paulsen have been working with the industry to make targeted reforms that encourage innovation and competition. Lack of transparency and growing inconsistencies have led to longer review times, increased red tape, and decreased patient access to life-saving treatments, and has threatened American competitiveness. However, the IOM's recommendation to replace the 510(k) program with an unknown and unspecified process would be disruptive to the medical device industry and potentially harmful to patients and consumers.

Klobuchar is the chair of the Senate Commerce Subcommittee on Competitiveness, Innovation, and Export Promotion, and she has met with FDA Commissioner Margaret Hamburg to discuss the medical device approval process. Last summer Klobuchar held a hearing with leading Minnesota innovators in the med-tech industry. Klobuchar credited Minnesota's medical device investors, entrepreneurs, and innovators for raising awareness about the need to streamline the approval process. Minnesota has over 400 medical device companies that employ over 35,000 Minnesotans. Earlier this year, Klobuchar and Scott Brown (R-MA) formed a new Senate Medical Technology Caucus, which aims to increase awareness about issues facing the medical technology sector, an industry that creates life-saving and life-enhancing innovations that improve patient care.

Franken, a member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, which oversees the FDA, has been advocating on behalf of Minnesota's medical device industry since coming to Washington. In August 2010, Franken held a summit in Minnesota with leading medical device manufacturers to hear their concerns regarding the FDA's regulatory process and then relayed industry concerns in a meeting with Commissioner Hamburg. Just yesterday, in a HELP Committee hearing on FDA regulation, Franken proposed several changes to the medical device review process to remove unnecessary barriers and foster innovation. HELP Committee Chairman Tom Harkin (D-IA) committed to working together to move these proposals forward. Earlier this year, Franken met with the head of the Center for Devices and Radiological Health, Dr. Jeff Shuren, who committed to soliciting and considering industry input before implementing recommendations based on the IOM report. Franken looks forward to working with Minnesota's medical device industry to ensure that the FDA fully understands the impact the IOM's recommendations would have on innovation and patient access to lifesaving devices.

As Co-Chair of the House Medical Technology Caucus, Paulsen has been a champion of medical technology innovation. He has recruited nearly 180 cosponsors to his bill to repeal the 2.3% innovation tax on medical devices. On June 2nd, Paulsen testified before the House Oversight and Government Reform Committee about the need to reform the FDA's pre-market review processes and is working to draft legislation to improve transparency and predictability at the agency.

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