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Klobuchar, Burr, Bennet Introduce Legislation to Boost Medical Device Innovation

Bill would reduce regulatory burdens that unnecessarily delay new medical devices from reaching the market

Washington, D.C. – U.S. Senators Amy Klobuchar (D-MN), Richard Burr (R-NC), and Michael Bennet (D-CO) today introduced legislation that would help boost medical innovation by reducing regulatory burdens that unnecessarily delay beneficial new medical products from reaching patients. The *Medical Device Regulatory Improvement Act* would help streamline the Food and Drug Administration's (FDA) regulation of medical devices to continue to spur innovation and help get new, lifesaving products to the market quicker without compromising consumer safety.

"It is critical that we don't allow regulatory burdens to get in the way of delivering lifesaving products to the patients who need them," Klobuchar said. "This legislation will help ensure that we have processes that promote safe, pioneering technologies that help save lives and create good jobs in Minnesota."

"In order to provide American patients access to the most cutting-edge medical therapies and advances, we need to fix what is broken at the FDA by restoring regulatory certainty and predictability," Senator Burr said. "By streamlining and ensuring the least burdensome approach to FDA's regulation of medical devices, we not only take a key step toward restoring America's leadership in the research and development of life-saving products, but uphold our promise to patients in North Carolina and around our nation to continue innovating on their behalf."

"Colorado is a hub of the life science industry and innovation, and we need to work with the FDA to ensure that it modernizes its regulatory system to foster innovation and drive the economy," said Bennet. "This bill would help provide our nation's medical device developers and manufacturers with the regulatory clarity and predictability that would give our patients the greatest access to lifesaving products and boost our national economic competitiveness."

Over the past few years the FDA's regulation has become increasingly longer and more difficult, delaying, and in some cases preventing, new and innovative devices from reaching the market. Recent studies showed that the average time to approve a 510(k) application has increased 43% from the 2003-2007 period to 2010, and the average time to approve a premarket approval (PMA) application has increased 75%. A recent survey of venture capitalist life sciences investors showed that almost 40% of investors are more likely to shift their operations and investments overseas because of FDA's regulatory challenges.

The senators' legislation would help streamline the FDA's regulation of medical devices by clarifying FDA's current least burdensome requirements. These provisions will ensure that when making regulatory decisions on medical devices, FDA focuses only on the relevant information during the decision-making process, considers appropriate alternatives to reduce the time, effort, and cost of reaching regulatory decisions, and uses all reasonable mechanisms to reduce review times when making these decisions.

Because current conflicts of interest restrictions are overly stringent, the FDA is having difficulty finding qualified experts to serve on advisory committees, which can contribute to unnecessary delays for patients. In response to this problem, the legislation would restore the appropriate balance to conflicts of interest requirements by requiring the FDA to be subject to the same conflicts of interest requirements as the rest of the federal government. Finally, the legislation would also direct the FDA to contract with an outside entity to conduct a thorough review of the management and regulatory processes at the FDA's Center for Devices and Radiological Health, including the impact on medical device innovation.

Klobuchar is the chair of the Senate Commerce Subcommittee on Competitiveness, Innovation, and Export Promotion, and has been a leader in the effort to cut red tape that threatens innovation in the medical device industry. After a December 2010 report surveyed over 200 medical technology companies and found that confusing and contradictory regulations are stifling innovation, Klobuchar pushed the Food and Drug Administration (FDA) to reform its slow and inconsistent 510(k) approval process for medical devices to maintain safety, protect patients, and encourage innovation. Klobuchar also founded the bipartisan Senate Medical Technology Caucus to increase awareness about issues facing the industry.

Bennet, a member of the Senate Committee on Health, Education, Labor and Pensions, sent a letter to FDA Commissioner Margaret Hamburg in August pushing for reformed FDA regulations that foster innovation and competitiveness and position the FDA to serve as a driver of the global economy. Following the letter, Hamburg joined Bennet to hear about innovation and advances in the bioscience industry in Colorado while touring the Colorado Science and Technology Park at Anschutz Medical Campus.

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