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Klobuchar Leads Bipartisan Letter to FDA Calling for Changes in Approval Process for Medical Devices

Washington, DC – U.S. Senator Amy Klobuchar announced today that she has sent a bipartisan, bicameral letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg regarding concerns over the agency's approval process for medical devices. Every year, medical devices are estimated to contribute $25 billion to our nation's economy, and are responsible for over 420,000 jobs. The United States has always been a leader in medical technology, but today many devices are debuting in Europe months or years before they are on the U.S. market. Approval times for medical devices have slowed dramatically, while poor communication and a lack of transparency have complicated the process. Klobuchar is co-chair of the Congressional Technology Caucus, whose members joined her on the letter, including U.S. Senator Al Franken and U.S. Representative Erik Paulsen.

In the letter, Klobuchar and the Caucus members state: **"Today, the United States accounts for 40 percent of the global medical technology market and the industry indirectly creates two million American jobs. Maintaining American leadership in this field is essential for jobs and for patients. Unless we make significant improvements to the predictability and transparency of the regulatory process, we will lose the industry, the jobs that go with it, and the innovation to transform our healthcare system."**

In the letter, the Klobuchar and the Caucus call for several changes to the FDA approval process, including:

- Recognizing and correcting the disparity between "FDA time" versus real time when tracking device approvals
- Considering potential benefits of harmonization with international testing standards
- Addressing the unintended consequences of the conflict of interest rules for advisory panels
- Creating a transparent tracking and review system for applications and clearance decisions

Even the President has recognized there are problems at the FDA in a report from the President's Job Council (files.jobs-council.com/jobscouncil/files/2011/10/JobsCouncil_InterimReport_Oct11.pdf), which stated: "Today, however, our medical innovation ecosystem is in jeopardy. Investment in the life sciences area is declining at an alarming rate because of the escalating cost, time and risk of developing new drugs and devices. While many factors have contributed to this decline - including challenges around reimbursement and the general state of the economy - an important factor is the uncertain FDA regulatory environment. These concerns come at a time when Europe, China, and India continue to entice companies to take their medical research and development enterprises abroad, putting at risk our ability to keep private investment and jobs here at home."

The letter from Klobuchar and the Caucus is below:

Dear Dr. Hamburg,

The bipartisan, bicameral Congressional Medical Technology Caucus, and other members of Congress join together to express our concerns about regulatory issues facing the medical device industry. This is an industry that has become increasingly important as dramatic improvements over the last decade have revolutionized healthcare and improved the quality of life for millions of Americans.

We share your commitment to ensuring safe and effective medical devices are available to patients. However, we are very concerned about recent declines in FDA performance. Increased review times, inconsistent expectations, and poor communication from the FDA are causing a lack of confidence and instability in the industry.

From the President's own Jobs Council report released this month

> "Today, however, our medical innovation ecosystem is in jeopardy. Investment in the life sciences area is declining at an alarming rate because of the escalating cost, time and risk of developing new drugs and devices. While many factors have contributed to this decline - including challenges around reimbursement and the general state of the economy - an important factor is the uncertain FDA regulatory environment. These concerns come at a time when Europe, China, and India continue to entice companies to take their medical research and development enterprises abroad, putting at risk our ability to keep private investment and jobs here at home." [1]

Dissatisfaction with the approval process is no longer just anecdotal: data shows the average time to approve a 510(k) application has increased by 43% from the 2003-2007 period to 2010.[2] The average time to approve a PMA application has increased 75%.[3] The total review times for both 510(k)s and PMAs are now actually longer than they were before the user fee program was instituted.[4]

It has also become significantly more costly to get new products approved. Companies spend an additional $520,000 a month as they wait for FDA approval of a 510(k) product and $740,000 each month for a PMA product.[5] This is simply unsustainable.

Today, the United States accounts for 40 percent of the global medical technology market[6] and the industry indirectly creates two million American jobs.[7] Maintaining American leadership in this field is essential for jobs and for patients. Unless we make significant improvements to the predictability and transparency of the regulatory process, we will lose the industry, the jobs that go with it, and the innovation to transform our healthcare system.

We recognize the need to balance risk and benefit; we all share patient safety as our primary concern, but there must be a "least burdensome approach" to achieve this without crippling an industry. We urge you to make every possible improvement to cut down device approval time by:

- Recognizing and correcting the disparity between "FDA time" versus real time when tracking device approvals
- Considering potential benefits of harmonization with international testing standards
- Addressing the unintended consequences of the conflict of interest rules for advisory panels
- Creating a transparent tracking and review system for applications and clearance decisions

These are just some of the ways the FDA can improve the process.

We appreciate the FDA's efforts in developing an Innovation Agenda and we recognize these changes will not take place overnight. However, stakeholders from innovators and patients, to investors and physicians all note that if the FDA does not restore regulatory certainty, predictability, and transparency, investment in the industry will continue to decline and this uniquely American success story could disappear.

Sincerely,

Anna G. Eshoo
Amy Klobuchar
Richard Lugar
Debbie Stabenow
Jay Inslee
Michael Honda
Betty McCollum
Bob Filner
Jason Altmire
Andre Carson
Susan Davis
Joe Donnelly

Erik Paulsen
Scott P. Brown
Al Franken
Brian Bilbray
David Drier
Dan Burton
Marlin Stutzman
Ken Calvert
Charles Bass
Mary Bono Mack
Michael Burgess
Todd Young

Pat Tiberi
Marsha Blackburn
John Kline
Charles Dent
Michele Bachmann
Aaron Schock
Anne Marie Buerkle
Bill Huizenga
Todd Rokita
Michael Rogers
Jim Gerlach
Michael R. Turner
Cathy McMorris Rodgers
Brett Guthrie
Glenn Thompson
Chris Gibson
Patrick Meehan

cc: Kathleen Sebelius, Secretary of Health and Human Services

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[1] United States. President's Council on Jobs and Competitiveness. *Taking Action, Building Confidence: Five Common Sense Initiatives to Boost Jobs and Competitiveness*, interim report, P.29. 2011. Online.
[2] FDA data analyzed by the Boston Consulting Group, *Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry*, February, 2011.
[3] Ibid.
[4] Ibid.
[5] Makower, Josh, M.D., Meer, Aabed, M.D., Denend, Lynn, November 2010. *FDA Impact on U.S. Medical Technology Innovation*, P. 28. http://www.advamed.org/NR/rdonlyres/040E6C33-380B-4F6B-AB58-9AB1C0A7A3CF/0/makowerreportfinal.pdf
[6] *Medical Technology Innovation Scorecard, the Race for Global Leadership*. PWC, January 2011, page 8.
[7] *State Economic Impact of the Medical Technology Industry*. Report prepared for AdvaMed by The Lewin Group, Inc. 2007