

Congress of the United States  
Washington, DC 20515

November 24, 2010

Dr. Margaret Hamburg  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Dr. Hamburg,

We are writing you to register our concerns related to the possible impact that recommended changes to the 510(k) review process may have on medical innovation. While we applaud the FDA for wanting to strengthen and improve the 510(k) process and carrying out a broad-based review, we also would like to encourage the FDA to review the impact of its recommendations on patient access as well as our state's economy.

We support the FDA's work to improve the process for the approval of safe and effective Class II medical devices but we must work to ensure that we continue to foster life saving innovation and growth. As members of the Minnesota delegation, we want to work with the FDA toward a larger goal of saving and improving patients' lives. Prompt access to new treatments and cures should be a key consideration in any proposed changes to the 510(k) process. Changes that may jeopardize that goal should not be made unless there is clear evidence that the changes are necessary to address a demonstrated public health problem.

We appreciate the dialogue that the FDA has started with Minnesota stakeholders including the town hall meeting that the FDA held in Bloomington, Minnesota earlier this year. As you know, Minnesota has an active and continually growing medical device industry. Minnesota has over 500 medical device companies that employ almost 35,000 Minnesotans. Their jobs pay nearly 50% more than the average statewide earnings.

Medical technology in America has been one of the few sustained bright spots in our economy over the last five years. Our state delegation wants to work with you to ensure that the medical technology industry will continue to play that role for decades to come. We look forward to working with you to help Minnesotans deliver life saving and sustaining technology to patients in Minnesota, throughout the United States, and the rest of the world.

Sincerely,

  
Senator Amy Klobuchar

  
Senator Al Franken


  
Rep. John Kline

  
Rep. Erik Paulsen

  
Rep. Betty McCollum

  
Rep. Keith Ellison

  
Rep. Michele Bachmann

  
Rep. Collin Peterson